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Guidebook for the Preparation of HACCP Plans

Additional copies of the Guidebook for the Preparation of HACCP Plans and the Generic HACCP Models are available from:

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TO THE USERS OF THESE VOLUMES

As some of you may know, the Food Safety and Inspection Service (FSIS) received a substantial package of comments on its Guidebook for Hazard Analysis and Critical Control Point (HACCP) Plan Development and the 13 Generic HACCP models, from a coalition of industry and trade associations. This package represents a large and thoughtful effort on the part of these organizations. FSIS intends to give it the careful attention and response that it deserves.

The comments included many technical suggestions for improvements in the FSIS documents. It also included reiteration of longstanding differing policy viewpoints that have been frequently discussed by the Agency and the regulated industry. For the first time, the comments revealed substantially differing expectations on the part of these organizations and FSIS with respect to the purpose of the FSIS documents and their intended use. We want to address some aspects of this latter point.

When the Pathogen Reduction/Hazard Analysis and Critical Control Point systems (PA/HACCP) final regulation was published on July 25, 1996, the DRAFT Guidebook was included as an appendix. The Generic Models, developed for FSIS under contract, were available shortly thereafter in April 1997. It was probably inevitable that there were significant differences between the final regulatory language of CFR Part 417 and the DRAFT Generic Models as they were developed independently. It would have been inappropriate for FSIS to discuss its final regulatory language with any outside group. The contractor was appropriately proceeding from what it knew best, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) documents on the subject of HACCP. Therefore, FSIS accepted that work product with full knowledge that significant revisions would be necessary.

As time passed, FSIS managers became increasingly uncomfortable with the situation in which its major technical assistance documents did not appropriately and completely inform the regulated industry of Agency expectations regarding regulatory compliance. Because the intended audience for these technical assistance materials was primarily the very small establishments, which the Agency believed to have the least HACCP-experience, the Agency began the systematic revision of the documents to overcome this problem. We targeted the summer of 1999 as the completion date for this effort.

FSIS now believes that others had very different ideas about the purpose and use of the documents than it did. As is consistently reiterated in the documents themselves, they are not designed to be used "as is." That is, they cannot be copied and used by an establishment to meet all the regulatory requirements of 9 CFR Part 417. Nor were they designed to be the ultimate teaching and training materials, as some would suggest. The development of ideal generic models is left to others who may have an interest in doing so. The generic models are not

designed to extend or further interpret existing regulations; rather, they are designed to send the user back to the regulations so he/she can become familiar with the requirements as well as the flexibility they permit. The generic models are not designed to present new or alternative methods of producing and processing meat and poultry products. That is also left to others with an interest in doing so.

FSIS envisioned that the generic models might be used in the following way: Suppose a HACCP team leader of a three-person HACCP team in a very small establishment attended a training course, but the others on his/her team were not able to do so. Suppose the HACCP training course met all the requirements of 417.7 but did not provide participants with much in the way of "take away materials" like workbooks, practical questions and answers, access to follow-up resources, etc., which the Research Triangle Institute (RTI) needs assessment indicated were so important to these establishments. The trained HACCP team leader returns to the establishment and begins the process of attempting to develop HACCP plans for the company's products and processes. He/she is quite confident that he/she has grasped the material presented in the training course and begins to work with this team immediately, while the concepts are fresh in his/her mind.

First, he/she has the rest of the team review the Canadian video and the Guidebook from FSIS so that all members of his team have a basic level of information.

The team members begin their work, and as they proceed, some questions arise as to whether what they have developed is appropriate. This is the point when FSIS expects the team to pick up the appropriate generic model and get a sense of whether they are on the right track. They should be able to determine whether the forms that they have developed, while different from the various ones in the generic models and not the same as what other companies use, are acceptable because they include the required information. They will also be able to discover what are some typical food safety hazards that are reasonably likely to occur, as explicitly defined in 417.2, and how to think through the problems that these hazards represent for their own products. They can see how critical limits might arise from existing regulatory requirements like the ones for rapid chilling of poultry products. They can also see that in the absence of settled regulatory requirements, there may be several sources of scientific expertise, and they can choose to make a conservative decision to provide a good margin of safety. They can find out the essential differences between monitoring and verification and have a basis for making their choices about verification activities and their frequencies. FSIS believes that these are useful, beneficial and worthwhile functions for which its generic models can be used.

FSIS is publishing these updated revisions of the generic models, beginning with the Guidebook and the Generic Model for Raw, Ground Product, because a large backlog of requests exists for these two documents. FSIS intends to publish revisions of all the generic models no later than September 30, 1999. Moreover, as a result of public consultation, it may publish an additional revision of some of these models, but given the backlog and the impending HACCP implementation date, we considered it important to get a version of these documents out now.

We hope that these documents are helpful.

Table of Contents

Introduction.....	3
Developing a HACCP Plan.....	3
Policy Notices.....	4
Preliminary Steps.....	5
1. Assemble the HACCP team, including one person who is HACCP-trained.....	5
2. Describe the food and its method of production and distribution.....	6
3. Develop and verify process flow diagram(s).....	6
4. Decide whether products can be grouped using the process categories.....	7
PRINCIPLE I: CONDUCT A HAZARD ANALYSIS.....	8
Biological Hazards.....	8
Chemical Hazards.....	8
Physical Hazards.....	9
PRINCIPLE II: IDENTIFY THE CRITICAL CONTROL POINTS.....	10
PRINCIPLE III: ESTABLISH CRITICAL LIMITS FOR EACH CRITICAL CONTROL POINT.....	11
PRINCIPLE IV: ESTABLISH MONITORING PROCEDURES.....	12
PRINCIPLE V: ESTABLISH CORRECTIVE ACTIONS.....	13
PRINCIPLE VI: ESTABLISH RECORDKEEPING PROCEDURES.....	14
PRINCIPLE VII: ESTABLISH VERIFICATION PROCEDURES.....	15
Validation.....	15
Ongoing verification.....	15
Reassessment.....	15
ATTACHMENTS	
Attachment 1 – PRODUCT DESCRIPTION.....	17
Attachment 2 – PROCESS FLOW DIAGRAM (Raw product-ground).....	18

Attachment 3 – PROCESS FLOW DIAGRAM (Beef Slaughter).....	19
Attachment 4 – Checklist of Questions (Hazard Analysis Process).....	20
Attachment 5 – HAZARD IDENTIFICATION/ PREVENTIVE MEASURES.....	24
Attachment 6 – HAZARD ANALYSIS – RAW PRODUCT, GROUND.....	25
Attachment 7 – HACCP PLAN DEVELOPMENT FORM: MONITORING PROCEDURES AND FREQUENCY.....	30
Attachment 8 – HACCP PLAN DEVELOPMENT FORM: CORRECTIVE ACTIONS.....	31
Attachment 9 – HACCP PLAN.....	32
Attachment 10 – List of Some Typical Records of a HACCP System in Operation.....	33

APPENDIX A

PART 417 – HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS.....	36
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APPENDIX B

References for HACCP Teams.....	45
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APPENDIX C

Livestock Carcasses and Poultry Carcasses Contaminated with Visible Fecal Material.....	49
Contents of HACCP Plans: Critical Control Points.....	53
Contents of HACCP Plans.....	56
Establishment Review of Product Production Records.....	59
HACCP Plan Requirements and Meat and Poultry Product Processing Categories; Policy Clarification.....	62
Listeria Monocytogenes Contamination of Ready-to-Eat Products.....	65

GUIDEBOOK FOR THE PREPARATION OF HACCP PLANS

Introduction

On July 25, 1996, the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) published a final rule on **Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems** (PR/HACCP). The PR/HACCP rule requires meat and poultry plants under Federal inspection to take responsibility for, among other things, reducing the contamination of meat and poultry products with disease-causing (pathogenic) bacteria. Reducing contamination with pathogenic bacteria is a key factor in reducing the number of deaths and illnesses linked to meat and poultry products. The Preamble to the final rule describes an overall system in which preventive and corrective measures are instituted at each stage of the food production process where food safety hazards could occur.

The HACCP requirements that plants must meet are set out in 9 CFR Part 417. HACCP is a scientific system for process control that has long been used in food production to prevent problems by applying controls at points in a food production process where hazards could be controlled, reduced or eliminated. A plant must have an effective HACCP system to comply with regulatory requirements and prevent adulteration of product.

The **HACCP** regulatory requirements become effective on different dates for plants of differing sizes:

Large plants – those with 500 or more employees – on January 26, 1998;

Smaller plants – those with fewer than 500 but at least 10 employees on January 25, 1999; and

Very small plants – those with fewer than 10 employees or annual sales less than \$2.5 million – on January 25, 2000.

Note: This **Guidebook** and other FSIS technical assistance materials are designed to assist establishments subject to the regulatory requirements of 9 CFR Part 417 in complying with those requirements. Part 417 is reproduced in **Appendix A**. These regulatory requirements are slightly different from the various explanations of HACCP developed by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF), the most recent version of which was published in 1997.

Developing a HACCP Plan

FSIS is providing this **Guidebook for the Preparation of HACCP Plans** to help plants develop and set up their HACCP systems. There are other FSIS publications, which may be helpful. This **Guidebook** is the most basic of the FSIS materials. FSIS has also developed thirteen generic models that plants can use to see if their specific plans are generally on target or help them get started. The generic models are more specific than this **Guidebook** and each one has at least one fully developed product example which establishment HACCP teams can study. However, even

though the generic models have more detailed information, they are not designed to be used “as is.” A company will still need to tailor the plan to suit the specific circumstances of its own production process.

Policy Notices

In order to clarify issues, which were raised in conjunction with the first implementation date, FSIS published a series of **Policy Notices** in the Federal Register. Copies are included as **Appendix C**. The issues addressed include:

Livestock Carcasses and Poultry Carcasses Contaminated with Visible Fecal Material (November 28, 1997)

Contents of HACCP Plans; Critical Control Points (January 30, 1998)

Contents of HACCP Plans (January 30, 1998)

Establishment Review of Product Production Records (March 6, 1998)

HACCP Plan Requirements and Meat and Poultry Product Processing Categories; Policy Clarification (April 1, 1998)

Listeria Monocytogenes Contamination of Ready-to-Eat Products (May 26, 1999)

Establishments may wish to refer to these **Policy Notices** if they need further clarification about the aspects of the regulations that are addressed.

In addition to written materials, FSIS has held a number of events to assist establishments in meeting regulatory requirements in a timely manner; these include both implementation conferences and technical assistance workshops.

Finally, FSIS has developed and put in place resources which are available to answer specific questions; the FSIS Technical Service Center operates a HACCP Helpline (1-800-233-3935 ext.2) which provides answers to technical questions from inspection personnel and establishments. Also FSIS has organized HACCP contacts in each of the states, to which establishments can turn for help with their specific problems. The District Office can provide information on the State HACCP Network.

Advice and assistance on developing HACCP systems can be obtained from many sources other than FSIS (use the Internet web site: **www.nal.usda.gov/fnic/foodborne/haccp/index.shtml**). FSIS encourages establishment officials to consult and use a variety of resources as they go about planning, documenting, and validating their HACCP systems. Also included in this **Guidebook** is a list of references that can be used by all HACCP teams that have been included as **Appendix B**. However, when HACCP regulations become effective in an establishment, it is the requirements of Part 417 that must be met. Establishment employees with a thorough understanding of HACCP concepts should still review the regulatory requirements of this part to

make sure they achieve compliance. This **Guidebook** has been revised to make it easier for users to relate its practical advice with the need to be in compliance with regulatory requirements.

Preliminary Steps

FSIS and most HACCP experts believe that a company will do a better job of HACCP plan development if it takes some **preliminary steps** before it attempts to apply the seven principles and write a plan. FSIS believes that a company should take the following steps to get started:

1. Assemble the HACCP team, including one person (consultant, employee, or other resource) who is HACCP-trained.
2. Describe the food and its method of production and distribution; identify the intended use and consumers of the products.
3. Develop and verify process flow diagram(s).
4. Decide whether products can be grouped using the process categories in 417.2(b)(1).

The first part of this **Guidebook** discusses how companies, especially small or very small companies, can go about taking these preliminary steps. Numbers 2-4 are parts of the regulatory requirements in §417.2(a).

1. Assemble the HACCP team, including one person who is HACCP-trained.

Assembling a HACCP team may seem like a daunting task, especially for the owner of a very small or family-centered company. However, FSIS strongly encourages companies to have more than one person working on the development of HACCP system(s). This is because HACCP system development is one of those tasks that are probably better done by more than one person, even in a very small company. HACCP is an overall process control system and we believe it takes a variety of different kinds of knowledge and experience to develop a good system. If your company has only a few people in it, they may all need to be on the HACCP team, because they all probably have multiple roles and responsibilities in the company's operations.

You should consider including on your HACCP team, some resources which may be outside your company. You may be able to get help from a trade association or from a local college, university or extension office which has people in it who know about HACCP process control systems. It is possible that companies which supply or receive your products and have already implemented HACCP may be interested in and willing to provide assistance. FSIS has offered technical assistance workshops to groups of plants that came together to a central location and worked through the process of system development in small steps.

One resource you **must include** is an individual who has been trained in HACCP in accordance with the requirements of Sec. 417.7. These requirements are that the individual has successfully completed a course in applying the seven principles of HACCP to meat or poultry product processing; the course needs to have included a segment on HACCP plan development for a specific product and a segment on record review. This **HACCP-trained individual** does not

need to be a company employee, but does need to be available to you for plan development and for certain other functions, like reassessing your HACCP plan(s).

2. Describe the food and its method of production and distribution; identify the intended use and consumers of the products.

The next preliminary step to take is to have the HACCP team describe the product(s) and their methods of production and distribution. If your team includes the people who know how things work in your operations, they should be able to do this quite easily. The important thing for them to keep in mind is that they need to include every step in the process. In order to help you make sure you include all the key information, we have prepared a form which could be used to accomplish this task. **Attachment 1** is this form and like all the forms in this **Guidebook**, its use is optional.

Whether you use the form or not, the following questions should be answered when you describe the product:

1. What is the common name of the product?
2. How is the product to be used?
3. What type of packaging encloses the product?
4. What is the length of shelf life of the product, at what temperature?
5. Where will the product be sold? *Who is the intended consumer and what is the intended use?
6. What labeling instructions are needed?
7. Is special distribution control needed?

* Regulatory requirement

After your team has described the products in words, they can move on to the next preliminary step.

3. Develop and verify process flow diagram(s).

A flow diagram is a simple schematic picture of the process you use in your plant to produce the product. You do not need any fancy equipment, such as a computer, to produce a flow diagram. However, it does need to be an accurate, clear sketch of the process used in your plant to make the product. **Attachment 2** is an example of a simple flow diagram for a relatively simple process; **Attachment 3** is a more complex flow diagram for a more complicated process. Either one would be an adequate flow diagram if it accurately pictured what was actually happening in the plant.

The best means to make sure your flow diagram is accurate is to have the HACCP team verify it by walking through the plant and making sure all the steps in the process you carry out are included in the flow diagram. Verifying the flow diagram is a step your team should be sure to do carefully. It is also a common means by which auditors or inspectors verify that a particular flow diagram is correct and complete.

When you are certain that you have an accurate flow diagram and your team has verified it, it is time to move to the final preliminary step.

4. Decide whether products can be grouped using the process categories in 417.2(b)(1).

This part of the regulations lists nine process categories into which meat and poultry production can be grouped; they and some examples are:

- (i) *Slaughter--all species: beef, swine, and poultry*
- (ii) *Raw product—ground: ground beef, ground pork, ground turkey*
- (iii) *Raw product--not ground: boneless cuts, steaks*
- (iv) *Thermally processed--commercially sterile: canned beef stew, Pasta with meat*
- (v) *Not heat treated--shelf stable: summer sausage, dry salami*
- (vi) *Heat treated--shelf stable: meat and poultry jerky, snack sticks*
- (vii) *Fully cooked--not shelf stable: hot dogs, wieners, roast beef, ham*
- (viii) *Heat treated but not fully cooked--not shelf stable: partially cooked patties, bacon*
- (ix) *Product with secondary inhibitors--not shelf stable: corned beef, cured beef tongue*

One way to cut down on the paperwork that is a part of HACCP system is to control all products in the same process category using a single HACCP plan. This is especially advantageous for very small establishments which may produce many different products. If those products differ only in characteristics that would not affect safety, e.g. the amount or kind of seasoning used (hot vs. mild), they are clearly in the same process category and may be covered by the same HACCP plan.

FSIS has developed eleven generic HACCP models for the processes listed above and two more specific processes, ***Mechanically Separated (Species)/ Mechanically Deboned Poultry and Irradiation*** (including all forms of approved irradiation procedures).

Now you have completed the preliminary steps that will prepare you for HACCP system development. It is time for your team to apply the seven principles of HACCP and develop your HACCP plan. The next seven sections (principles) of this **Guidebook** will take you through this process.

PRINCIPLE I: CONDUCT A HAZARD ANALYSIS

The first principle of HACCP is to conduct a hazard analysis. Part 417 contains definitions as well as specific provisions which affect how your HACCP team must go about conducting its hazard analysis. Before beginning the process, your team should review the definitions of **food safety hazard** and **preventive measure**, and look specifically at the requirements of 417.2(a).

- A. Conducting a hazard analysis is generally considered to be a two-step process. The first step is to identify the threats to human health, which might be introduced into meat and poultry products as those products are produced. These **hazards** are usually grouped into three categories: Biological (including microbiological), Chemical, and Physical.

1. Biological Hazards

Biological hazards are living organisms that can make food unsafe to eat. Biological hazards may be bacterial, parasitical, or viral. Biological hazards are frequently associated with the raw materials from which meat and poultry products are made, including the animals and birds, which are primary components. However, biological hazards may be introduced during the processing of meat and poultry products: from the people who are involved in the processing; from the environment in which the foods are processed; from other ingredients in the products; or from the processes themselves.

Identifying the biological hazards to which your production processes might be subjected is clearly a difficult and important task—one that requires all the expertise that your HACCP team can bring to it. Currently, there is a great deal of emphasis on microbial hazards associated with meat and poultry products. Some of the major pathogens that may be associated with meat and poultry products are: *Salmonella*, *Campylobacter jejuni*, *Escherichia coli* 0157:H7, *Listeria monocytogenes*, *Clostridium botulinum*, *Staphylococcus aureus*, and *Yersinia enterocolitica*. For details, refer to NACMCF document reference 14 listed in Appendix B.

2. Chemical Hazards

Chemical hazards may be the result of something naturally occurring in foods or added during the processing of foods. Harmful chemicals have been associated with both acute cases of foodborne illness and chronic illness.

Naturally occurring chemical hazards are those that are natural constituents of foods and not the result of environmental, industrial, or other contamination. They include aflatoxins, mycotoxins and shellfish toxins.

Added chemical hazards are those which are intentionally or sometimes unintentionally added to food during the growing, harvesting, storage, processing, packaging, or distribution phases of production. This group of chemical hazards is very broad and might include components of animal feed or drinking water, animal drugs, pesticides, food ingredients themselves, or chemicals used in the processing establishment such as lubricants, cleaners, paints, and coatings.

3. Physical Hazards

A physical hazard is a physical component of a food that is unexpected and may cause illness or injury to the person consuming the food. Foreign materials such as glass, metal, or plastic are familiar physical hazards in meat and poultry products, usually found because a process or a piece of equipment has not been properly controlled while the food was being produced.

There are a number of situations that can contribute to physical hazards in foods; they include:

- Contaminated raw materials;
- Poorly designed or poorly maintained facilities and equipment;
- Contaminated packaging materials; and,
- Inattention to details by employees with key responsibilities.

- B. This first step in identifying hazards which might be associated with your production process might be considered like a “brainstorming” session. Your HACCP team should use the flow diagram and product description, which you created in your preliminary steps, and systematically think about what could occur at each step in the process. **Attachment 4** is a checklist of questions which might help your team to be as thorough as possible in considering the hazards which might be associated with your process.
- C. The second step in performing a hazard analysis is to identify preventive measures that could be used to control each hazard. Preventive measures are the physical, chemical, or other means that can be used to control a food safety hazard. **Attachment 5** is a form which you can use to go through your process systematically, identify the hazards which might occur at each step in the process and the preventive measures which might be used to prevent, eliminate, or reduce each hazard to an acceptable level which you can use in conjunction with the checklist. More than one preventive measure may be needed to control a food safety hazard and more than one food safety hazard may be controlled by a specific preventive measure.
- D. **Attachment 6** is a hazard analysis, which has been completed for a simple raw, ground process. When developing your hazard analysis, be sure to remember that supporting documentation for the decisions reached by the team is very important and a regulatory requirement [§ 417.5(a)(1)]. The supporting documentation can consist of the regulatory citation if the critical limit is based on a regulation, a scientific paper, study, or in-plant study. Historical information about the process can also be used. This information should be summarized as part of the supporting documentation for the team’s decisions. When making determinations about whether a hazard is reasonably likely to occur, it is helpful to list the actual hazard or organism of concern. For example, metal contamination from equipment, *Salmonella*, *Escherichia coli* O157:H7, *Campylobacter jejuni*, *Listeria monocytogenes* or other specific pathogenic hazards, or a specific residue that is known to occur in a like product. You will find this information very helpful when yearly reassessment, a deviation, or an unforeseen hazard occurs.

We cannot overemphasize how important it is to do a good job on your hazard analysis. This is often a difficult and time-consuming step, and one that requires all the various technical and scientific resources you can obtain. You can refer to the NACMCF DRAFT document - “*FSIS Microbiological Hazard Identification Guide for Meat and Poultry Components of Products Produced by Very Small Plants*”, August 1999 (Appendix B, Reference 14)”. We know that doing a good job and taking your time here is worth the effort. You cannot expect to develop a good HACCP system if you have not been careful and thorough in your hazard analysis.

PRINCIPLE II: IDENTIFY THE CRITICAL CONTROL POINTS

The second HACCP principle is to identify the critical control points (CCPs) in the process. A CCP is a point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.

So far, in developing the HACCP plan, your HACCP team has identified biological, chemical, and physical hazards in the raw materials and the ingredients you use as well as in the steps of your process. For each food safety hazard reasonably likely to occur, you have identified a preventive measure. Your next step is to find the point or points in the process where these preventive measures should be applied.

Fortunately, a great deal of work has already been done in identifying points where control can be applied in a process. Many points are commonly recognized in various food processing and production systems. Some common points where control can be applied in your process include:

- Chilling to temperatures that minimize microbial growth;
- Cooking to specific temperatures for exact times in order to destroy microbial pathogens;
- Product formulations, such as the addition of cultures or adjustment of pH or water activity;
- Processing procedures such as filling and sealing cans; and,
- Slaughter procedures such as evisceration or antimicrobial interventions.

These are just a few examples of measures that may be CCPs. There are many more possibilities. Different facilities preparing the same food can differ in the number and types of CCPs they choose to use. This is to be expected.

The FSIS generic models, as well as other generic models, give you some ideas about what CCPs might work in the various process categories which are discussed. Your team needs to remember that these are just ideas designed to help get your team thinking creatively and carefully about your own processes and how you want to control them with your HACCP system.

Note: Identifying CCPs is one area in which there are differences between the regulatory requirements of Part 417 and the NACMCF guidance materials (reference 13). The latter include the use of a Decision Tree; the Decision Tree approach is not necessary for you to meet regulatory requirements; however, the thought process may be helpful. You must make sure that your HACCP system meets regulatory requirements.

PRINCIPLE III: ESTABLISH CRITICAL LIMITS FOR EACH CRITICAL CONTROL POINT

HACCP principle three instructs your team to establish critical limits for each preventive measure you will carry out at each CCP. This step involves establishing a criterion that must be met for each preventive measure associated with a CCP. Part 417 defines a critical limit as: the maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.

Critical limits are the boundaries of safety for preventive measures put in place at CCPs. A critical limit will usually be a reading or observation such as a temperature, a time, a product property such as water activity, or a chemical property such as available chlorine, salt concentration, or pH. Critical limits need to be exact and specific; HACCP plans should not include ranges as critical limits.

Many critical limits for identified CCPs have been established, either through regulatory requirements or through the technical and scientific literature, which are the bases of production processes. Your HACCP team will probably be familiar with many of these established critical limits such as: the minimum internal temperature to which products must be cooked; the time which may elapse while product is being cooled to a specific temperature; the maximum dimensions of any metal fragments which could be found in products. These critical limits **must be met** if product safety is to be maintained.

When deciding what your critical limits should be, there are several sources to consider. First are the regulatory requirements, which apply to your processes. **These must be met.** For example, if you produce cooked beef products, you must have critical limits that meet the current FSIS regulatory requirements for those products. There may be other sources of critical limits, such as the times and temperatures that you use in making the products you produce. These may be based on scientific and technical information from studies or food processing textbooks or they may be based on family recipes that have been passed down from one generation to the next and have scientifically been shown to produce safe product. Critical limits may be drawn from specific challenge studies or from recognized experts. In any case, you need to establish a critical limit for each preventive measure you intend to apply at your CCPs.

There are two types of critical limits. A critical limit can be an *upper limit* where a set amount or level cannot be exceeded. A critical limit can also be a *lower limit* where a minimum amount is required to produce the safe effect. To address the hazard in ground product of metal fragments from the grinding equipment, the *upper* critical limit for the preventive measure could be no sharp metal fragments more than 1/32 inch. A grinding room temperature of 50° F to help control pathogen growth is another kind of *upper* critical limit. An example of a *lower* critical limit would be the addition of an acidifier to inhibit bacterial growth.

PRINCIPLE IV: ESTABLISH MONITORING PROCEDURES

To carry out HACCP principle four, your team needs to establish monitoring procedures. Monitoring procedures are those things, which are done routinely, either by employee or by mechanical means, which, measure the process at a given CCP, and create a record for future use. Some monitoring procedures are employee observations or checks, such as checking the documentation accompanying incoming materials. Some monitoring procedures are records from instruments, such as recording thermometers.

Continuous monitoring is always preferred when it is feasible. When it is not possible, then your HACCP team will need to decide what will be their non-continuous monitoring procedures and how frequently they will be performed. There are several issues to consider when deciding the frequency of non-continuous monitoring checks; the most important is that the procedures must be performed sufficiently often to accurately reflect that the process is under control. Expert advice from people with knowledge of practical statistics and statistical process control will be important in making your decisions about frequency.

Another factor that HACCP teams must consider is the capacity of the plant to take corrective actions when monitoring procedures reveal that there have been deviations from critical limits. When monitoring procedures show that there has been a deviation from a critical limit, corrective actions need to be applied to all the potentially noncomplying product. This usually includes all the product produced since the time of the last successful monitoring procedure result. So, if your monitoring procedure was to perform a physical check on arriving product, and your team decided to do this only once per shift, a deviation from the critical limit would mean that you needed to apply corrective actions to all the product which had arrived during the shift.

Another matter for your HACCP team to consider when they are deciding on what should be the monitoring procedures and how frequently they should be performed is the need for rapid, real time feedback. Generally, physical and chemical procedures are preferred over microbial approaches for monitoring because they provide more rapid feedback.

Monitoring procedures need to be well planned and effective because of the potentially serious consequences of loss of control. Employees monitoring CCPs should be trained in the technique to be used to monitor each preventive measure or control. They should fully understand the purpose and importance of monitoring and accurately report monitoring activities and results. They must have complete access to the CCP being monitored and to the process-monitoring instruments being used.

The persons performing monitoring must record exact values where exact values are indicated, not “yes/no” or “OK” observations. This means that if the critical limit is a minimum internal temperature of 160° F, the observations on the monitoring record would be recorded as “162 °F,” “163°F” rather than “yes” or “OK.”

Attachment 7 is a simple form, which your team might use to help them decide on monitoring procedures and their frequency.

PRINCIPLE V: ESTABLISH CORRECTIVE ACTIONS

HACCP principle five says: Establish corrective actions to be taken when monitoring shows that there is a deviation from a critical limit. In addition, § 417.3 identifies the four features of corrective actions that FSIS regulators will be checking; they are:

1. Has the cause of the deviation been identified and eliminated?;
2. Will the CCP be under control after the corrective action has been taken?;
3. Have measures to prevent recurrence of the deviation been established?; and,
4. Do the corrective action procedures make sure that no product, which is injurious to health or otherwise adulterated because of the deviation enters commerce?

HACCP is a preventive system to correct problems before they affect the safety of the food products people actually consume. Deviations from critical limits will occur; therefore, you need to have a plan to make sure those deviations do not lead to unsafe products. Planned corrective actions are the way you do this. Your HACCP team needs to understand how important it is to carefully carry out this principle.

For each CCP, your team needs to devise a standardized set of actions that company employees will follow when there is a deviation from a critical limit. These are some questions they might ask in developing corrective actions:

How will people be informed when the deviation occurs? If a person is performing the monitoring procedure, who will that person contact?

Who will be responsible for controlling the product that may have been affected by the deviation? How should that person decide how much product needs to be controlled?

Who will be involved in deciding what to do about the product which might have been affected by the deviation?

How will we decide what was the cause of the deviation? If we need technical experts outside the company, how do we get them?

Once we have figured out what was the cause of the deviation, who will be involved in deciding how to get the process back in control and prevent recurrence of the deviation?

If our HACCP trained individual is not available in the plant immediately, how can we get HACCP expertise to help decide if our plan needs to be modified?

Who in the company needs to sign off on any modifications to our plan?

Who will be responsible for keeping the records of everything we do in response to a deviation from a critical limit at this CCP?

If any person who has a responsibility in our corrective action plan is not available, who will be the back-up?

Is this set of corrective actions feasible at all times?

Attachment 8 is a simple form to help your HACCP team make sure they have developed appropriate corrective actions for each CCP. Part 417 includes regulatory requirements, which must be followed when a deviation not covered by a specific corrective action occurs or if an unforeseen hazard occurs. Your team should study § 417.3(b) so that you know what to do when this happens. In many ways, the actions to be taken will be generally similar to what you plan to do at any specific CCP—get control of the product, figure out what was the cause and how to keep it from happening again, decide whether to modify your HACCP plan, etc. Your team should at least think about how you want to handle these situations.

PRINCIPLE VI: ESTABLISH RECORDKEEPING PROCEDURES

HACCP principle number 6 is to establish effective recordkeeping procedures that document the HACCP system. The regulatory recordkeeping requirements for meat and poultry establishments are found in § 417.5 and are quite comprehensive. Your team should review them carefully.

Even though people often complain about it, recordkeeping is an essential feature of a HACCP system and must be planned and carried out as carefully as any other element. This principle requires the development and maintenance of records about both plan development and the operation of the system. In a study on HACCP prepared by the Department of Commerce it was clear that, without recordkeeping, problems were more likely to recur.

Even though people may grumble about keeping records, the practice can be made sensible and suitable for the operation in question. Clearly more sophisticated records will be required for more complex operations. One way to approach development of the recordkeeping requirements of your HACCP system is to review the records you already keep and see if they are suitable, in their present form or with minor modifications, to serve the purposes of your HACCP system. The best recordkeeping system is usually the simplest one that can be easily integrated into the existing operation.

When you are setting up your recordkeeping system, think about who will be in the best position to make the record entry, who will need to review the record prior to shipping, plus, when and where will be the best place to keep the records. Think about making simple understandable forms that will work well in your situation. Make sure your employees know exactly what is expected if they are responsible for making a record entry. It is extremely important that they sign and date the records at the time the specific event occurs.

Records do not need to be in any particular format. Often HACCP plans are presented in a tabular form. **Attachment 9** is an example of a blank HACCP Plan form in a typical format. **Attachment 10** is a list of some typical records of a HACCP system in operation. The

PR/HACCP regulation also includes a requirement for preshipment review in § 417.5(c). This step can provide you added assurance that you have done everything in your HACCP plan before you ship the product. There are examples in each of the generic models on how this can be accomplished.

PRINCIPLE VII: ESTABLISH VERIFICATION PROCEDURES

HACCP principle seven is to establish verification procedures to make sure the plan is working correctly.

Your team needs to decide on what procedures the plant will perform to verify that the HACCP system is working effectively *and* how often these actions will be performed. Verification uses methods, procedures, or tests in addition to those used in monitoring to see whether the HACCP system is in compliance with the HACCP plan or whether the HACCP plan needs modification. There are three types of verification.

Validation is the initial phase in which the plan is tested and reviewed. The choices made while working through the preliminary steps and HACCP principles must be repeatedly tested and shown to prevent or control identified hazards in the “real world”. In this phase, microbial or residue testing can be used effectively to verify that the process is in control and is producing acceptable product. Such testing provides clear evidence that the techniques and methods adopted by the plant to control hazards are not just effective in theory but will work in *this* specific plant.

Ongoing verification ensures that the HACCP plan is working effectively on a day-to-day basis. This type of verification includes such tasks as calibrating monitoring instruments, observing monitoring activities and corrective actions, and reviewing HACCP records to see that they are being made and kept according to the plan.

Reassessment is an overall review of the plan that must be performed at least annually, or whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Reassessment is similar to validation in that it considers whether the plan is adequate in general rather than focusing on the plan's daily operations. It is also similar to validation in that it must be done by a HACCP-trained person.

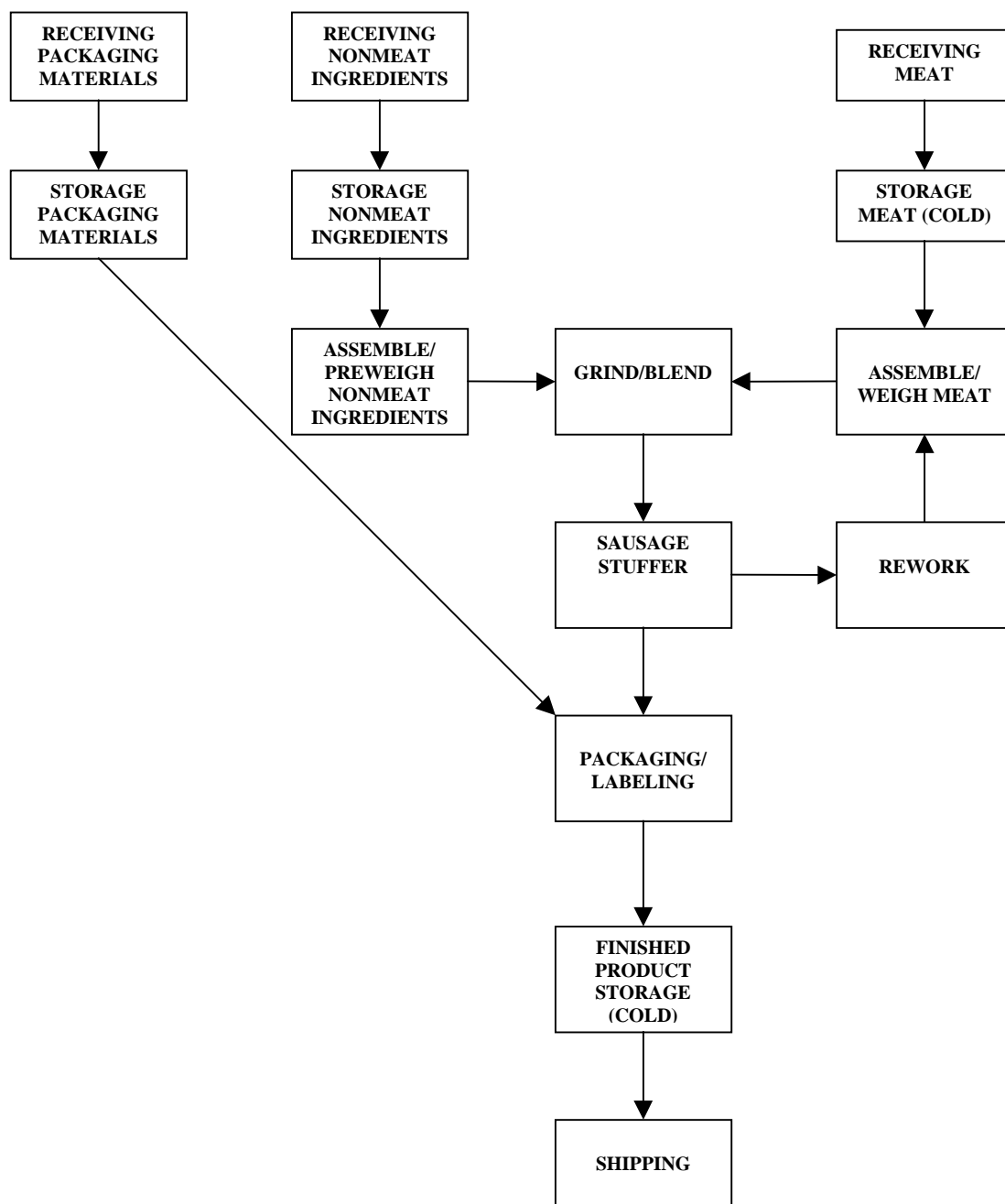
ATTACHMENTS

PRODUCT DESCRIPTION**Attachment 1****PROCESS CATEGORY: SLAUGHTER****PRODUCT: BEEF**

1. COMMON NAME?	BEEF; BEEF VARIETY MEATS
2. HOW IS IT TO BE USED?	CARCASSES; VARIETY MEATS
3. TYPE OF PACKAGE?	CARCASSES – NONE; VARIETY MEATS – 50 POUND BOXES
4. LENGTH OF SHELF LIFE, AT WHAT TEMPERATURE?	7 DAYS AT 40° F
5. WHERE WILL IT BE SOLD? CONSUMERS? INTENDED USE?	WHOLESALE TO DISTRIBUTORS ONLY
6. LABELING INSTRUCTIONS?	KEEP REFRIGERATED
7. IS SPECIAL DISTRIBUTION CONTROL NEEDED?	KEEP REFRIGERATED

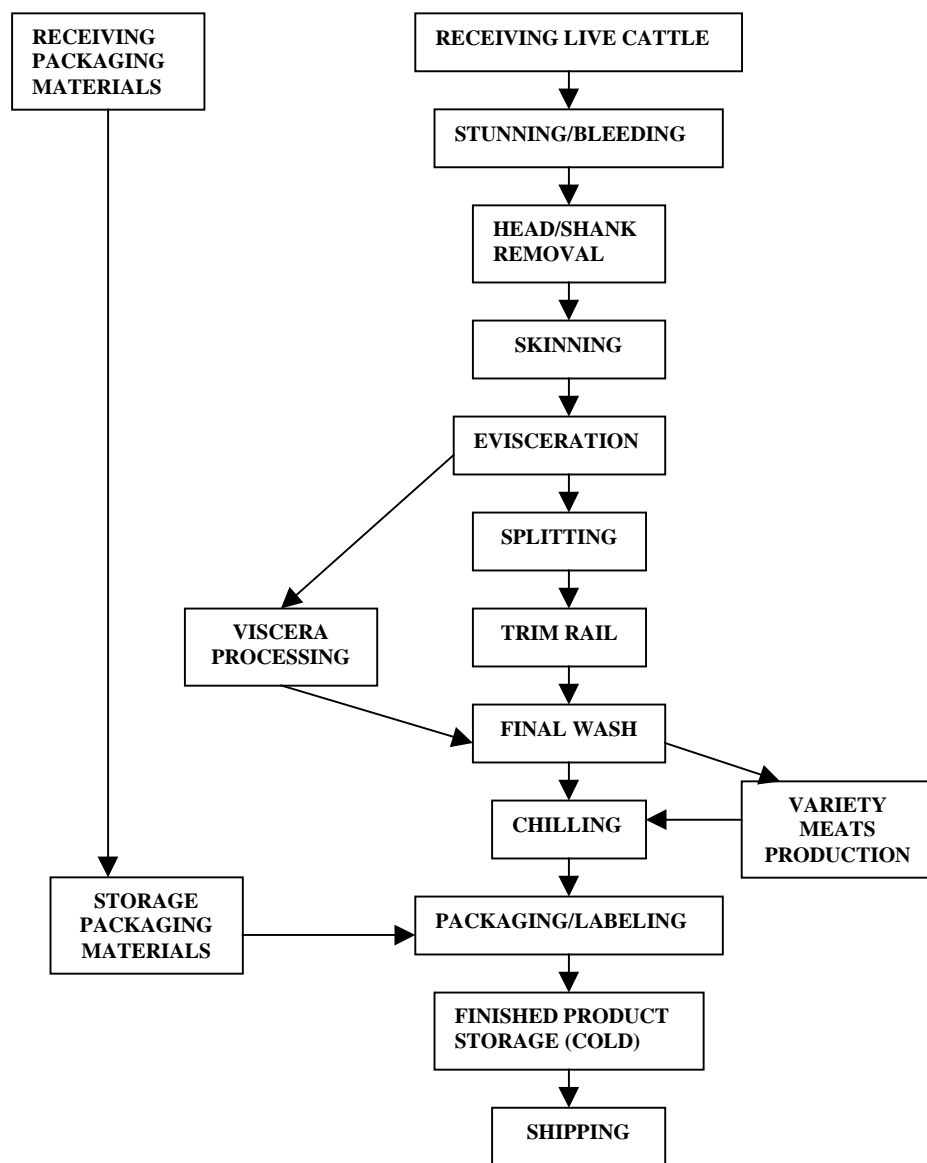
PROCESS FLOW DIAGRAM Attachment 2

PROCESS CATEGORY: RAW PRODUCT, GROUND PRODUCT: FRESH PORK SAUSAGE



PROCESS FLOW DIAGRAM

Attachment 3

PROCESS CATEGORY: SLAUGHTER**PRODUCT: BEEF**

Checklist of Questions

(Hazard Analysis Process)

Attachment 4

This point in hazard analysis consists of asking a series of questions that are appropriate to each step in the flow diagram. The hazard analysis should question the effect of a variety of factors on the safety of the food.

1. Ingredients

Does the food contain any sensitive ingredients that are likely to present microbiological hazards (e.g. *Salmonella*, *Staphylococcus aureus*), chemical hazards (e.g., aflatoxin, antibiotic, or pesticide residues) or physical hazards (stones, glass, bone, metal)?

2. Intrinsic factors of food

Physical characteristics and composition (e.g., pH, type of acids, fermentable carbohydrates, water activity, preservatives) of the food during and after preparation which can cause or prevent a hazard.

Which intrinsic factors of the food must be controlled in order to ensure food safety?

Does the food permit survival or multiplication of pathogens and/or toxin formation before or during preparation?

Will the food permit survival or multiplication of pathogens and/or toxin formation during subsequent steps of preparation, storage, or consumer possession?

Are there other similar products in the market place? What has been the safety record for these products?

3. Procedures used for preparation/processing

Does the preparation procedure or process include a controllable step that destroys pathogens or their toxins? Consider both vegetative cells and spores.

Is the product subject to recontamination between the preparation step (e.g., cooking) and packaging?

4. Microbial content of the food

Is the food commercially sterile (i.e., low acid canned food)?

Is it likely that the food will contain viable sporeforming or nonsporeforming pathogens?

What is the normal microbial content of the food stored under proper conditions?

Does the microbial population change during the time the food is stored before consumption?

Does that change in microbial population alter the safety of the food?

5. Facility design

Does the layout of the facility provide an adequate separation of raw materials from ready-to-eat foods?

Is positive air pressure maintained in product packaging areas? Is this essential for product safety?

Is the traffic pattern for people and moving equipment a potential source of contamination?

6. Equipment design

Will the equipment provide the time/temperature control that is necessary to meet critical limits?

Is the equipment properly sized for the volume of food that will be prepared?

Can the equipment be controlled so that the variation in performance will be within the tolerances required to produce a safe food?

Is the equipment reliable or is it prone to frequent breakdowns?

Is the equipment designed so that it can be cleaned and sanitized?

Is product contamination with hazardous substances, e.g., glass, likely to occur?

What product safety devices such as time/temperature integrators are used to enhance consumer safety?

7. Packaging

Does the method of packaging affect the multiplication of microbial pathogens and/or the formation of toxins?

Is the packaging material resistant to damage, thereby preventing the entrance of microbial contamination?

Is the package clearly labeled “Keep Refrigerated” if this is required for safety?

Does the package include instructions for the safe handling and preparation of the food by the consumer?

Are tamper-evident packaging features used?

Is each package legibly and accurately coded to indicate production lot?

Does each package contain the proper label?

8. Sanitation

Can the sanitation practices that are employed impact upon the safety of the food that is being prepared?

Can the facility be cleaned and sanitized to permit the safe handling of foods?

Is it possible to provide sanitary conditions consistently and adequately to ensure safe foods?

9. Employee health, hygiene, and education

Can employee health or personal hygiene practices impact the safety of the food being prepared?

Do the employees understand the food preparation process and the factors they must control to ensure safe foods?

Will the employees inform management of a problem, which could impact food safety?

10. Conditions of storage between packaging and the consumer

What is the likelihood that the food will be improperly stored at the wrong temperature?

Would storage at improper temperature lead to a microbiologically unsafe food?

11. Intended use

Will the food be heated by the consumer?

Will there likely be leftovers?

12. Intended consumer

Is the food intended for the general public, i.e., a population that does not have an increased risk of becoming ill?

Is the food intended for consumption by a population with increased susceptibility to illness (e.g., infants, the elderly, the infirm, and immuno compromised individuals)?

	HAZARD IDENTIFICATION/PREVENTIVE MEASURES		
	PROCESS CATEGORY:		
	PRODUCT:		
	PROCESS STEP	FOOD SAFETY HAZARD	PREVENTIVE MEASURE(S)

APPROVED BY:_____ **Date:**_____

HAZARD ANALYSIS – RAW PRODUCT, GROUND – Fresh Pork Sausage

Attachment 6

Process Step	Food Safety Hazard	Reasonably Likely to Occur?	Basis	If Yes in Column 3, What Measures Could be Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level?	Critical Control Point
Receiving - Meat	Biological: Pathogens - microbial (<i>Salmonella</i> , <i>Escherichia coli</i> 0157:H7)	Yes	Either pathogen may be present on incoming raw product.	Letters of guaranty that supplier meets base line criteria or in process control of room temperature or storage temperature to prevent growth	1B
	Chemical – None				
	Physical – Foreign materials	No	Plant records show that there has been no incidence of foreign materials in products received into the plant.		
Receiving – Nonmeat Ingredients/Packaging Materials	Biological – None				
	Chemical – Not acceptable for intended use	No	Letters of guaranty are received from all suppliers of nonmeat ingredients and packaging materials.		
	Physical – Foreign materials	No	Plant records demonstrate that foreign material contamination has not occurred during the past several years.		

HAZARD ANALYSIS – RAW PRODUCT, GROUND

Attachment 6

Process Step	Food Safety Hazard	Reasonably Likely to Occur?	Basis	If Yes in Column 3, What Measures Could be Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level?	Critical Control Point
Storage (Cold) - Meat	Biological – Pathogens (List those specific to the product)	Yes	Pathogens are reasonably likely to grow in this product if temperature is not maintained at or below a level sufficient to preclude the growth.	Maintain product temperature at or below a level sufficient to preclude pathogen growth.	2B
	Chemical – None				
	Physical – None				
Storage – Nonmeat Ingredients/Packaging Materials	Biological – None				
	Chemical – None				
	Physical – None				
Assemble/Pre-weigh Nonmeat Ingredients	Biological – None				
	Chemical – None				
	Physical – None				
Assemble/Weigh Meat	Biological – None				
	Chemical – None				
	Physical – None				

HAZARD ANALYSIS – RAW PRODUCT, GROUND

Attachment 6

Process Step	Food Safety Hazard	Reasonably Likely to Occur?	Basis	If Yes in Column 3, What Measures Could be Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level?	Critical Control Point
Grind/Blend	Biological - None				
	Chemical – None				
	Physical – Metal contamination	Yes	Plant records show that during the grinding process metal contamination is likely to occur.	In-line magnets are installed on the stuffing lines.	3P
Sausage Stuffer	Biological – None				
	Chemical – None				
	Physical – None				
Rework	Biological – Pathogens	Yes	Rework can be a source of continuing inoculation with pathogens.	Rework is condemned or used in a cooked product at the plant. If it will not be used that day or is coded and not mixed so that the identity and total time in plant or process can be determined.	4B
	Chemical- None				
	Physical – None				

HAZARD ANALYSIS – RAW PRODUCT, GROUND

Attachment 6

Process Step	Food Safety Hazard	Reasonably Likely to Occur?	Basis	If Yes in Column 3, What Measures Could be Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level?	Critical Control Point
Packaging/Labeling	Biological: Pathogens – parasitic (<i>Trichina</i>)	Yes	<i>Trichina</i> has historically occurred in raw pork products.	Labels that clearly indicate this is a raw product, along with cooking instructions, and the safe food handling statement.	5B
	Chemical – None				
	Physical – Metal contamination	Yes	Metal contamination that may have come into the establishment or is contaminated during the grinding process must be removed.	Functional metal detector is on-line in the packaging/labeling area to remove metal contamination.	6P
Finished Product Storage (Cold)	Biological – Pathogens	Yes	Pathogens are reasonably likely to grow in this product if temperature is not maintained at or below a level sufficient to preclude their growth.	Maintain product temperature at or below a level sufficient to preclude pathogen growth.	7B
	Chemical – None				
	Physical - None				

HAZARD ANALYSIS – RAW PRODUCT, GROUND

Attachment 6

Process Step	Food Safety Hazard	Reasonably Likely to Occur?	Basis	If Yes in Column 3, What Measures Could be Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level?	Critical Control Point
Shipping	Biological – None				
	Chemical- None				
	Physical – None				

HACCP PLAN DEVELOPMENT FORM: MONITORING PROCEDURES AND FREQUENCY

PROCESS CATEGORY:

PRODUCT:

PROCESS STEP/CCP	CRITICAL LIMITS	MONITORING PROCEDURES *(WHO/WHAT/WHEN/HOW)

* 417.5(b), 417.2(6), 417.2(4)- Who refers to the requirement that records must be initialed; When – to the time the specific event occurs; What – the measurement to determine compliance at the CCP; and How - the method used to monitor the CCP.

HACCP PLAN DEVELOPMENT FORM: CORRECTIVE ACTIONS

PROCESS CATEGORY:

PRODUCT:

PROCESS STEP/CCP	CRITICAL LIMITS	MONITORING PROCEDURES (WHO/WHAT/WHEN/HOW)	*CORRECTIVE ACTIONS

*Be sure to include your planned actions to address all parts of § 417.3.

Attachment 9

HACCP PLAN					
PROCESS CATEGORY: _____					
PRODUCT EXAMPLE: _____					
CCP# and Location	Critical Limits	Monitoring Procedures and Frequency	HACCP Records	Verification Procedures and Frequency	Corrective Actions

Signature: _____

Date: _____

List of Some Typical Records of a HACCP System in Operation

1. Ingredients

- Records from all monitored CCPs.
- Supplier certification documenting compliance with establishment's specifications.
- Establishment's audit records verifying supplier compliance.
- Storage temperature record for temperature-sensitive ingredients.
- Storage time records of limited shelf-life ingredients.

2. Preparation

- Records from all monitored CCPs.
- Records verifying the continued adequacy of the food preparation procedures.

3. Packaging

- Records indicating compliance with specifications for packaging materials.
- Records indicating compliance with sealing specifications.

4. Finished product

- Sufficient data and records to establish the efficacy of barriers in maintaining product safety.
- Sufficient data and records to establish the safe shelf-life of the product if age of product can affect safety.
- Documentation of the adequacy of the HACCP procedures from an authority knowledgeable of the hazards involved and necessary controls.

5. Storage and distribution

- Temperature records.
- Records showing no product shipped after shelf-life date on temperature-sensitive products.

6. Deviation and corrective action

- Records of all actions taken following deviations at a CCP.
- Reassessment records and modifications to the HACCP plan indicating approved revisions and changes in ingredients, formulations, preparation, packaging, and distribution control, as needed.

7. Employee training

- Records indicating that employees responsible for implementation of the HACCP plan understand the hazards, controls, and procedures.

APPENDIX A

PART 417--HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

§ 417.1 Definitions.

For purposes of this part, the following definitions shall apply:

Corrective action. Procedures to be followed when a deviation occurs.

Critical control point. A point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.

Critical limit. The maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.

Food safety hazard. Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

HACCP System. The HACCP plan in operation, including the HACCP plan itself.

Hazard. SEE Food Safety Hazard.

Preventive measure. Physical, chemical, or other means that can be used to control an identified food safety hazard.

Process-monitoring instrument. An instrument or device used to indicate conditions during processing at a critical control point.

Responsible establishment official. The individual with overall authority on-site or a higher level official of the establishment.

§ 417.2 Hazard Analysis and HACCP Plan.

(a) Hazard analysis. (1) Every official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment. A food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls.

(2) A flow chart describing the steps of each process and product flow in the establishment shall be prepared, and the intended use or consumers of the finished product shall be identified.

(3) Food safety hazards might be expected to arise from the following:

- (i) Natural toxins;
- (ii) Microbiological contamination;
- (iii) Chemical contamination;
- (iv) Pesticides;
- (v) Drug residues;
- (vi) Zoonotic diseases;
- (vii) Decomposition;
- (viii) Parasites;
- (ix) Unapproved use of direct or indirect food or color additives; and
- (x) Physical hazards.

(b) The HACCP plan. (1) Every establishment shall develop and implement a written HACCP plan covering each product produced by that establishment whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, based on the hazard analysis conducted in accordance with paragraph (a) of this section, including products in the following processing categories:

- (i) Slaughter--all species.
- (ii) Raw product--ground.
- (iii) Raw product--not ground.
- (iv) Thermally processed--commercially sterile.
- (v) Not heat treated--shelf stable.
- (vi) Heat treated--shelf stable.
- (vii) Fully cooked--not shelf stable.

(viii) Heat treated but not fully cooked--not shelf stable.

(ix) Product with secondary inhibitors--not shelf stable.

(2) A single HACCP plan may encompass multiple products within a single processing category identified in this paragraph, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed in paragraph (c) of this section are essentially the same, provided that any required features of the plan that are unique to a specific product are clearly delineated in the plan and are observed in practice.

(3) HACCP plans for thermally processed/commercially sterile products do not have to address the food safety hazards associated with microbiological contamination if the product is produced in accordance with the requirements of part 318, subpart G, or part 381, subpart X, of this chapter.

(c) The contents of the HACCP plan. The HACCP plan shall, at a minimum:

(1) List the food safety hazards identified in accordance with paragraph (a) of this section, which must be controlled for each process.

(2) List the critical control points for each of the identified food safety hazards, including, as appropriate:

(i) Critical control points designed to control food safety hazards that could be introduced in the establishment, and

(ii) Critical control points designed to control food safety hazards introduced outside the establishment, including food safety hazards that occur before, during, and after entry into the establishment;

(3) List the critical limits that must be met at each of the critical control points. Critical limits shall, at a minimum, be designed to ensure that applicable targets or performance standards established by FSIS, and any other requirement set forth in this chapter pertaining to the specific process or product, are met;

(4) List the procedures, and the frequency with which those procedures will be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;

(5) Include all corrective actions that have been developed in accordance with § 417.3(a) of this part, to be followed in response to any deviation from a critical limit at a critical control point; and

(6) Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.

(7) List the verification procedures, and the frequency with which those procedures will be performed, that the establishment will use in accordance with § 417.4 of this part.

(d) Signing and dating the HACCP plan. (1) The HACCP plan shall be signed and dated by the responsible establishment individual. This signature shall signify that the establishment accepts and will implement the HACCP plan.

(2) The HACCP plan shall be dated and signed:

(i) Upon initial acceptance;

(ii) Upon any modification; and

(iii) At least annually, upon reassessment, as required under § 417.4(a)(3) of this part.

(e) Pursuant to 21 U.S.C. 456, 463, 608, and 621, the failure of an establishment to develop and implement a HACCP plan that complies with this section, or to operate in accordance with the requirements of this part, may render the products produced under those conditions adulterated.

§ 417.3 Corrective actions.

(a) The written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure:

(1) The cause of the deviation is identified and eliminated;

(2) The CCP will be under control after the corrective action is taken;

(3) Measures to prevent recurrence are established; and

(4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.

(b) If a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment shall:

(1) Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met;

(2) Perform a review to determine the acceptability of the affected product for distribution;

(3) Take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce;

(4) Perform or obtain reassessment by an individual trained in accordance with § 417.7 of this part, to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan.

(c) All corrective actions taken in accordance with this section shall be documented in records that are subject to verification in accordance with § 417.4(a)(2)(iii) and the recordkeeping requirements of § 417.5 of this part.

§ 417.4 Validation, Verification, Reassessment.

(a) Every establishment shall validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis, and shall verify that the plan is being effectively implemented.

(1) Initial validation. Upon completion of the hazard analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCP's, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan. Validation also encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities.

(2) Ongoing verification activities. Ongoing verification activities include, but are not limited to:

(i) The calibration of process-monitoring instruments;

(ii) Direct observations of monitoring activities and corrective actions; and

(iii) The review of records generated and maintained in accordance with § 417.5(a)(3) of this part.

(3) Reassessment of the HACCP plan. Every establishment shall reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; personnel; packaging; finished product distribution systems; or, the intended use or consumers of the finished product. The reassessment shall be performed by an individual trained in accordance with § 417.7 of this part. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan no longer meets the requirements of § 417.2(c) of this part.

(b) Reassessment of the hazard analysis. Any establishment that does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur shall reassess the adequacy of the hazard analysis whenever a change occurs that could reasonably affect whether a food safety hazard exists. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; packaging; finished product distribution systems; or, the intended use or consumers of the finished product.

§ 417.5 Records.

(a) The establishment shall maintain the following records documenting the establishment's HACCP plan:

(1) The written hazard analysis prescribed in § 417.2(a) of this part, including all supporting documentation;

(2) The written HACCP plan, including decision making documents associated with the selection and development of CCP's and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.

(3) Records documenting the monitoring of CCP's and their critical limits, including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s), product name or identity, or slaughter production lot. Each of these records shall include the date the record was made.

(b) Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the date and time recorded, and shall be signed or initialed by the establishment employee making the entry.

(c) Prior to shipping product, the establishment shall review the records associated with the production of that product, documented in accordance with this section, to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of product. Where practicable, this review shall be conducted, dated, and signed by an individual who did not produce the record(s), preferably by someone trained in accordance with § 417.7 of this part, or the responsible establishment official.

(d) Records maintained on computers. The use of records maintained on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

(e) Record retention. (1) Establishments shall retain all records required by paragraph (a)(3) of this section as follows: for slaughter activities for at least one year; for refrigerated

product, for at least one year; for frozen, preserved, or shelf-stable products, for at least two years.

(2) Off-site storage of records required by paragraph (a)(3) of this section is permitted after six months, if such records can be retrieved and provided, on-site, within 24 hours of an FSIS employee's request.

(f) Official review. All records required by this part and all plans and procedures required by this part shall be available for official review and copying.

§ 417.6 Inadequate HACCP Systems.

A HACCP system may be found to be inadequate if:

- (a) The HACCP plan in operation does not meet the requirements set forth in this part;
- (b) Establishment personnel are not performing tasks specified in the HACCP plan;
- (c) The establishment fails to take corrective actions, as required by § 417.3 of this part;
- (d) HACCP records are not being maintained as required in § 417.5 of this part; or
- (e) Adulterated product is produced or shipped.

§ 417.7 Training.

(a) Only an individual who has met the requirements of paragraph (b) of this section, but who need not be an employee of the establishment, shall be permitted to perform the following functions:

(1) Development of the HACCP plan, in accordance with § 417.2(b) of this part, which could include adapting a generic model that is appropriate for the specific product; and

(2) Reassessment and modification of the HACCP plan, in accordance with § 417.3 of this part.

(b) The individual performing the functions listed in paragraph (a) of this section shall have successfully completed a course of instruction in the application of the seven HACCP principles to meat or poultry product processing, including a segment on the development of a HACCP plan for a specific product and on record review.

§ 417.8 Agency verification.

FSIS will verify the adequacy of the HACCP plan(s) by determining that each HACCP plan meets the requirements of this part and all other applicable regulations. Such verification may include:

- (a) Reviewing the HACCP plan;
 - (b) Reviewing the CCP records;
 - (c) Reviewing and determining the adequacy of corrective actions taken when a deviation occurs;
 - (d) Reviewing the critical limits;
 - (e) Reviewing other records pertaining to the HACCP plan or system;
 - (f) Direct observation or measurement at a CCP;
 - (g) Sample collection and analysis to determine the product meets all safety standards;
- and
- (h) On-site observations and record review.

APPENDIX B

References for HACCP Teams

1. Agriculture Canada. *Food Safety Enhancement Program – HACCP Implementation Manual*. Camelot Drive, Nepean, Ontario, Canada, 1996.
2. American Meat Institute Foundation. *HACCP: The Hazard Analysis and Critical Control Point System in the Meat and Poultry Industry*. Washington, D.C., 1994.

Useful sections in particular are:

Chapter 3 – microbiological hazards, pp. 15-26

Chapter 4 – chemical hazards, pp. 27-32

Chapter 5 – physical hazards, pp. 33-35

Appendix A – NACMCF HACCP

Appendix C – Model HACCP plans

3. Baker, D.A. *Application of Modeling in HACCP Plan Development*. Int. J. Food Microbiol. 25:251-261, 1995.
4. Corlett, D.A., Jr. and Stier, R.F. *Risk Assessment within the HACCP System*. Food Control 2:71-72, 1991.
5. Council for Agriculture Science and Technology. *Risks Associated with Foodborne Pathogens*. February 1993.
6. Easter, M.C., et al. *The Role of HACCP in the Management of Food Safety and Quality*. J. Soc. Dairy Technol. 47:42-43, 1994.
7. Environmental Protection Agency. *Tolerances for Pesticides in Foods*. Title 40, Code of Federal Regulations, Part 185. U.S. Government Printing Office, Washington, D.C., 1998.
8. Food and Drug Administration. *The Food Defect Action Levels*. FDA/CFSAN. Washington, D.C., 1998.
9. Food and Drug Administration. *Fish and Fishery Products Hazards and Control Guide --Get Hooked on Seafood Safety*. Office of Seafood. Washington, D.C., 1994.
10. International Commission on Microbiological Specification for Foods. *HACCP in Microbiological Safety and Quality*. Blackwell Scientific Publications, Oxford, 1988.

Useful sections in particular are:

Chapter 10 – raw meat and poultry, pp. 176-193

Chapter 11 – roast beef, pp. 234-238

Chapter 11 – canned ham, pp. 238-242

11. International Commission on Microbiological Specification for Foods. *Microorganisms in Foods 4. Application of Hazard Analysis and Critical Control Point (HACCP) Systems to Ensure Microbiological Safety and Quality*. Blackwell Scientific Publications, Boston, 1989
12. National Advisory Committee on Microbiological Criteria for Foods. *March 20, 1992 -- Hazard Analysis and Critical Control Point System*. Int. J. Food Microbiol. 16: 1-23, 1993.
13. National Advisory Committee on Microbiological Criteria for Foods. Adopted August 14, 1997-- *Hazard Analysis and Critical Control Point Principles and Application Guidelines*. J. Food Protect. 61(9): 1246-1259, 1998.
14. National Advisory Committee on Microbiological Criteria for Foods. DRAFT document - *FSIS Microbiological Hazard Identification Guide for Meat and Poultry Components of Products Produced by Very Small Plants*. 1-22, August 1999.
15. National Advisory Committee on Microbiological Criteria for Foods. *June 1993 -- Report on Generic HACCP for Raw Beef*. Food Microbiol. 10: 449-488, 1994.
16. National Research Council. *An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients*. National Academy Press, Washington, D.C., 1985.

Useful sections in particular are:

- Chapter 4 – microbiological hazards, pp. 72-103
- Chapter 9 – raw meat, pp. 193-199
- Chapter 9 – processed meats, pp. 199-216

17. Notermans, S., et al. *The HACCP Concept: Identification of Potentially Hazardous Microorganisms*. Food Microbiol. 11:203-214, 1994.
18. Pierson M.D. and Dutson, T. Editors. *HACCP in Meat, Poultry, and Fish Processing*. Blackie Academic & Professional. Glasgow, 1995.

Useful sections in particular are:

- Chapter 4 – meat and poultry slaughter, pp. 58-71
- Chapter 5 – processed meats, pp. 72-107
- Chapter 7 – risk analysis, pp. 134-154
- Chapter 13 – predictive modeling, pp. 330-354

19. Pierson, M.D. and Corlett, D.A., Jr. Editors. *HACCP Principles and Applications*. Van Nostrand Reinhold, New York, 1992.
20. Stevenson, K.E. and Bernard, D.T. Editors. *HACCP: Establishing Hazard Analysis Critical Control Point Programs., A Workshop Manual*. The Food Processors Institute, Washington, D.C., 1995.

Useful sections in particular are:

Chapter 11 – forms for hazard analysis, CCPs, critical limits, HACCP master sheet, example HACCP for breaded chicken

21. Stevenson, K.E. and Bernard, D.T. Editors. *HACCP: A Systematic Approach to Food Safety*. 3rd Edition. The Food Processors Institute, Washington, D.C., 1999.
22. Tompkin, R.B. *The Use of HACCP in the Production of Meat and Poultry Products*. J. Food Protect. 53(9): 795-803, 1990.
23. Tompkin, R.B. *The Use of HACCP for Producing and Distributing Processed Meat and Poultry Products*. In *Advances in Meat Research*. Volume 10. *Hazard Analysis Critical Control Point in Meat, Poultry and Seafoods*. Chapman & Hall, 1995.

APPENDIX C

Livestock Carcasses and Poultry Carcasses Contaminated With Visible Fecal Material

[Federal Register: November 28, 1997 (Volume 62, Number 229)]
[Rules and Regulations]
[Page 63254-63255]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr28no97-2]

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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 301, 307, 308, 310, 318, 381, 416, and 417

[Docket No. 97-067N]

Livestock Carcasses and Poultry Carcasses Contaminated With
Visible Fecal Material

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice on complying with food safety standards under the **HACCP**
system regulations.

SUMMARY: The Food Safety and Inspection Service is publishing this notice to assure that the owners and operators of federally inspected slaughter establishments are aware that the Agency views its "zero tolerance" for visible fecal material as a food safety standard. Fecal material is a vehicle for microbial pathogens, and microbiological contamination is a food safety hazard that is reasonably likely to occur in the slaughter production process. In controlling microbiological contamination, a hazard analysis and critical control point plan for slaughter must be designed, among other things, to ensure that, by the point of post-mortem inspection of livestock carcasses or when poultry carcasses enter the chilling tank, no visible fecal material is present.

FOR FURTHER INFORMATION CONTACT: Patricia F. Stolfa, Assistant Deputy Administrator, Regulations and Inspection Methods, Food Safety and Inspection Service, Washington, DC 20250-3700; (202) 205-0699.

SUPPLEMENTARY INFORMATION: The Food Safety and Inspection Service (FSIS) administers a regulatory program under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.) to protect the health and welfare of consumers by preventing the distribution of livestock products and poultry products that are unwholesome, adulterated, or

misbranded. A livestock product or poultry product is adulterated under any of a number of circumstances, including the following: if it bears or contains any poisonous or deleterious substance which may render it injurious to health, unless when the substance is not an added substance, the quantity in or on the article does not ordinarily render it injurious to health; if it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise

[[Page 63255]]

unfit for human food; or if it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health (21 U.S.C. 453(g)(1), (g)(3), and (g)(4) and 601(m)(1), (m)(3), and (m)(4)). Both the FMIA and the PPIA include requirements for government inspection and prohibit transactions in products required to be inspected unless they have been ``inspected and passed'' or if they are adulterated (21 U.S.C. 458(a)(2) and 610(c)).

FSIS enforces a ``zero tolerance'' standard for visible fecal material on carcasses and carcass parts at inspected establishments that slaughter livestock or poultry. This standard is reflected in the Agency's regulations under the FMIA and the PPIA (9 CFR chapter III, subchapter A and subchapter C, respectively), which require (among other things) that establishments handle livestock carcasses and carcass parts to prevent contamination with fecal material and promptly remove contamination if it occurs (Sec. 310.18) and that establishments prevent poultry carcasses contaminated with visible fecal material from entering the chilling tank (Sec. 381.65(e)). When inspection program personnel observe fecal material at post-mortem livestock inspection or thereafter (i.e., at or after the final rail) under the FMIA or when poultry carcasses are about to enter the chilling tank or thereafter (i.e., at any point after the final pre-chiller wash) under the PPIA, they condemn affected carcasses and carcass parts unless the contamination is removed in accordance with regulatory requirements.

The Agency is publishing this notice to assure that the owners and operators of federally inspected slaughter establishments are aware that FSIS regards its zero tolerance for visible fecal material as a food safety standard under both the FMIA and the PPIA. Reiterating the Agency's position is particularly appropriate now, as federally inspected establishments prepare to comply with the hazard analysis and critical control point (**HACCP**) system regulations (part 417). ¹

\1\ Part 417 requirements, as well as pathogen reduction performance standards for Salmonella in establishments that slaughter cattle, swine, chickens, or turkeys, prepare ground beef or fresh pork sausage, or process ground chicken or turkey (Secs. 310.25(b) and 381.94(b)) will apply as of January 26, 1998, in establishments with 500 or more employees; January 25, 1999, in establishments with 10 or more but fewer than 500 employees (unless the establishment has annual sales of less than \$2.5 million); and January 25, 2000, in establishments with fewer than 10 employees or annual sales of less than \$2.5 million.

The essence of FSIS's position is that fecal material is a vehicle for microbial pathogens, and microbiological contamination is a food safety hazard that is reasonably likely to occur in the slaughter production process (Sec. 417.2(a) and (b)). Consequently, **HACCP** plans must control for microbiological contamination at slaughter, and to meet the zero tolerance standard, an establishment's controls must (among other things) include limits that ensure that no visible fecal material is present by the point of post-mortem inspection of livestock carcasses or before poultry carcasses enter the chilling tank (Sec. 417.2(c)).

In the Pathogen Reduction-**HACCP** Systems final rule (61 FR 38806, July 25, 1996), FSIS explained the reasoning underlying its position on fecal contamination, and at the beginning of this year, FSIS addressed the role of its zero tolerance for visible fecal material on poultry carcasses in the final rule that codified the standard under the PPIA (62 FR 5139, February 4, 1997). Preparation for implementation of the **HACCP** system regulations has not changed the Agency's conclusions about the appropriateness of this standard, under the FMIA as well as the PPIA.

As the Agency stated in the Pathogen Reduction-**HACCP** Systems final rule (61 FR 38837):

In slaughter establishments, fecal contamination of carcasses is the primary avenue for contamination by pathogens. Pathogens may reside in fecal material and ingesta, both within the gastrointestinal tract and on the exterior surfaces of animals going to slaughter. Therefore, without care being taken in handling and dressing procedures during slaughter and processing, the edible portions of the carcass can become contaminated with bacteria capable of causing illness in humans. Additionally, once introduced into the establishment environment, the organisms may be spread from carcass to carcass.

Because the microbial pathogens associated with fecal contamination are the single most likely source of potential food safety hazard in slaughter establishments, preventing and removing fecal contamination and associated bacteria are vital responsibilities of slaughter establishments. Further, because such contamination is largely preventable, controls to address it will be a critical part of any slaughter establishment's **HACCP** plan. Most slaughter establishments already have in place procedures designed to prevent and remove visible fecal contamination.

As noted in the zero tolerance final rule and confirmed today with respect to livestock as well as poultry, establishments that process animals must adopt controls that they can demonstrate are effective in reducing the occurrence of microbial pathogens, including controls that prevent the fecal contamination of carcasses (62 FR 5140). Under the **HACCP** system regulations, critical control points to eliminate contamination with visible fecal material are predictable and essential components of all slaughter establishments' **HACCP** plans. Initial validation of a **HACCP** plan for slaughter and monitoring thereunder, as verified and documented in establishment records, must demonstrate the effective operation of the plan's controls on a continuing basis (Secs. 417.3(a), 417.4, and 417.5).

FSIS personnel will continue to verify compliance with the zero tolerance standard in slaughter establishments that are subject to part 417 requirements. The Agency will use visual observations and other

Guidebook

findings by FSIS personnel in evaluating the effectiveness of an establishment's preventive controls and corrective actions for fecal contamination (Secs. 417.6 and 417.8). The presence of visible fecal contamination on livestock carcasses presented for post-mortem inspection or poultry carcasses entering the chilling tank will mean that establishment controls have failed; repeated failures will evidence that establishment corrective actions have failed to prevent recurrence and, thus, possible system inadequacy.

In addition to enforcing the zero tolerance for visible fecal material, FSIS will use the results of establishment testing for generic *E. coli* (*Escherichia coli* Biotype I, as already required by Sec. 310.25(a) or Sec. 381.94(a)) in assessing how well an establishment is controlling its slaughter and dressing processes to prevent fecal contamination. The pathogen reduction performance standards for *Salmonella* (Secs. 310.25(b) and 381.94(b)), which FSIS will enforce through its own testing program, will complement the zero tolerance standard and *E. coli* testing.

Done at Washington, D.C., on November 18, 1997.
Thomas J. Billy,
Administrator.
[FR Doc. 97-31176 Filed 11-26-97; 8:45 am]
BILLING CODE 3410-DM-P

Contents of HACCP Plans: Critical Control Points

[Federal Register: January 30, 1998 (Volume 63, Number 20)]
[Rules and Regulations]
[Page 4560-4562]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr30ja98-2]

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 417

[Docket No. 97-082N]

Contents of HACCP Plans; Critical Control Points

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Compliance with the HACCP system regulations.

SUMMARY: The Food Safety and Inspection Service (**FSIS**) is publishing this document to ensure that the owners and operators of federally inspected establishments are aware that the identification of appropriate critical

[[Page 4561]]

control points is crucial to complying with the Agency's regulations on hazard analysis and critical control point (HACCP) systems. The HACCP system regulations require that a HACCP plan list critical control points for each food safety hazard identified as reasonably likely to occur in the production process. The number of critical control points will depend upon the production process and the hazard, but a HACCP plan must specify as critical control points the points, steps, or procedures at which control can be applied and, as measured by critical limits, occurrence of the hazard can be prevented, eliminated, or reduced to an acceptable level, and at a minimum, the critical limits must be designed to ensure that applicable targets or performance standards established by **FSIS**, and any other requirement in the Agency's regulations pertaining to the specific process or product, are met. These requirements implement **FSIS**'s judgment that whenever a food safety hazard is reasonably likely to occur in the production process, by applying control measures, the establishment can at least reduce the hazard to an acceptable level, even if it cannot entirely prevent or eliminate its occurrence.

FOR FURTHER INFORMATION CONTACT: Patricia F. Stolfa, Assistant Deputy Administrator, Regulations and Inspection Methods, Food Safety and Inspection Service, Washington, DC 20250-3700; (202) 205-0699.

SUPPLEMENTARY INFORMATION: The Food Safety and Inspection Service (**FSIS**) administers a regulatory program under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.) to protect the health and welfare of consumers by preventing the distribution of livestock products and poultry products that are unwholesome, adulterated, or misbranded. To further the goal of reducing the risk of foodborne illness from meat and poultry products to the maximum extent possible, **FSIS** issued the Pathogen Reduction-Hazard Analysis and Critical Control Point (HACCP) Systems final rule (61 FR 38806, July 25, 1996).

The HACCP system regulations, part 417, ¹ require that every federally inspected establishment conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards (Sec. 417.2(a)). Whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, the establishment must develop and implement a HACCP plan, or plans, to control those hazards (Sec. 417.2(b)). Although it is possible that a hazard analysis conducted in accordance with the regulations will reveal no food safety hazard that is reasonably likely to occur, as the Agency stated when it issued the regulations, **FSIS** is not aware of any meat or poultry production process that can be deemed, categorically, to pose no likely hazards (61 FR 38824). ²

\1\ Part 417 requirements will apply as of January 26, 1998, in establishments with 500 or more employees; January 25, 1999, in establishments with 10 or more but fewer than 500 employees (unless the establishment has annual sales of less than \$2.5 million); and January 25, 2000, in establishments with fewer than 10 employees or annual sales of less than \$2.5 million.

\2\ Food safety hazards include any biological, chemical, or physical property that may cause a food to be unsafe for human consumption (Sec. 417.1).

For purposes of part 417, a critical control point (CCP) is a point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels (Sec. 417.1.) Every HACCP plan must ``list the critical control points for each of the identified food safety hazards, including, as appropriate:''

(i) Critical control points designed to control food safety hazards that could be introduced in the establishment, and

(ii) Critical control points designed to control food safety hazards introduced outside the establishment, including food safety hazards that occur before, during, and after entry into the establishment * * *

(Sec. 417.2(c)(2)). The plan also must comply with the related requirements to specify the critical limits (maximum and minimum values) to be met at CCP's, the corrective actions to be followed in response to deviations from critical limits at CCP's, and the monitoring and verification procedures to ensure appropriate corrective actions if and when those deviations occur (Secs. 417.1, 417.2(c), 417.3(a), and 417.4(a)). At a minimum, critical limits must be designed

to ensure that applicable targets or performance standards established by **FSIS**, and any other requirement in **FSIS**'s regulations (9 CFR chapter III) pertaining to the specific process or product, are met (Sec. 417.2(c)(3)).

It has come to **FSIS**'s attention that in developing HACCP plans, some persons are viewing CCP's so narrowly that they risk noncompliance with regulatory requirements. **FSIS** is concerned that some establishments may be relying solely on HACCP concepts and theory, without evaluating CCP's in accordance with regulatory requirements. The Agency is publishing this notice to ensure that the owners and operators of federally inspected establishments are aware that the identification of appropriate critical control points is crucial.

The number of critical control points will depend upon the production process and the hazard. **FSIS** will treat failure to specify at least one CCP for each food safety hazard identified in accordance with the regulations as reasonably likely to occur as a failure to develop and implement a HACCP plan that complies with Sec. 417.2 (Sec. 417.2(e)). The only exception, as specified in Sec. 417.2(b)(3), is for food safety hazards associated with microbiological contamination: HACCP plans that cover thermally processed/commercially sterile products produced in accordance with the current canning regulations (part 318, subpart G, or part 381, subpart X) need not, at this time, address microbial hazards.³

\3\ **FSIS** intends to convert the canning regulations to performance standards, which are more consistent with HACCP (61 FR 38824).

FSIS anticipates that to operate in accordance with part 417, many establishments will find that for each identified hazard, they need more than one CCP, particularly if they are producing raw products. The Agency believes that depending upon a single CCP increases establishment exposure to production-disrupting corrective actions that affect large amounts of product. While **FSIS** is not prepared to say that compliance cannot be achieved with a single CCP when, for example, a product is treated sufficiently to be shelf stable, even though it is not commercially sterile, the Agency is concerned that establishments may be viewing CCP's too restrictively to ensure compliance with the regulations.

The part 417 requirements addressed in this notice implement the Agency's conclusion that whenever a food safety hazard is reasonably likely to occur in the production process, even if an establishment cannot entirely prevent or eliminate occurrence of the hazard, by applying control measures, the establishment can at least reduce it to an acceptable level. Part 417 requires all federally inspected establishments to take the prudent, preventive approach and develop systematic measures for controlling such hazards.

[[Page 4562]]

Done at Washington, D.C., on: January 26, 1998.
Thomas J. Billy,
Administrator.
[FR Doc. 98-2297 Filed 1-29-98; 8:45 am]
BILLING CODE 3410-DM-P

Contents of HACCP Plans

[Federal Register: January 30, 1998 (Volume 63, Number 20)]
[Rules and Regulations]
[Page 4562]
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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 417

[Docket No. 97-074N]

Contents of HACCP Plans

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Compliance with the HACCP system regulations.

SUMMARY: The Food Safety and Inspection Service is publishing this document to ensure that the owners and operators of federally inspected establishments are aware that its hazard analysis and critical control point (HACCP) system regulations require that an HACCP plan be a self-contained document. In particular, the Agency does not view references to good manufacturing practices, or establishment actions in accordance with good manufacturing practices, as satisfying the requirements for the contents of an HACCP plan. Among other things, an HACCP plan must list the critical control points for each food safety hazard reasonably likely to occur in the production process, the critical limits that must be met at each of the critical control points, and the procedures, and frequency with which they will be performed, that will be used to monitor each critical control point to ensure compliance with critical limits and to verify that the plan is being effectively implemented. An HACCP plan also must identify the corrective actions to be followed in response to deviations from critical limits at critical control points.

FOR FURTHER INFORMATION CONTACT: Patricia F. Stolfa, Assistant Deputy Administrator, Regulations and Inspection Methods, Food Safety and Inspection Service, Washington, DC 20250-3700; (202) 205-0699.

SUPPLEMENTARY INFORMATION: The Food Safety and Inspection Service (FSIS) administers a regulatory program under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.) to protect the health and welfare of consumers by preventing the distribution of livestock products and poultry products that are unwholesome, adulterated, or misbranded. To further the goal of reducing the risk of foodborne

illness from meat and poultry products to the maximum extent possible, FSIS issued the Pathogen Reduction-Hazard Analysis and Critical Control Point (HACCP) Systems final rule (61 FR 38806, July 25, 1996). As amended by that rule, FSIS's regulations require federally inspected establishments to take preventive and corrective measures at each stage of the food production process where food safety hazards occur.

The regulations on HACCP systems, part 417,* require a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures an establishment can apply to control them (Sec. 417.2(a)(1)) and, whenever this analysis reveals one or more such hazards, development and implementation of a written HACCP plan (Sec. 417.2(b)(1)). In Sec. 417.2(c), the regulations specify minimum requirements for the contents of each HACCP plan, including requirements to list the food safety hazards for each process; list the critical control points for each of the identified hazards; list the critical limits that must be met at each of the critical control points; list the procedures, and frequency with which they will be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits; and list the verification procedures, and the frequency with which they will be performed, that the establishment will use in accordance with Sec. 417.4 (i.e., to verify that the plan is being effectively implemented) (paragraphs (c)(1), (c)(2), (c)(3), (c)(4), and (c)(7) of Sec. 417.2). In addition, a HACCP plan must include all corrective actions that have been developed in accordance with Sec. 417.3(a), which requires the identification of the corrective action to be followed in response to a deviation from a critical limit (Sec. 417.2(c)(5)).

* Part 417 requirements will apply as of January 26, 1998, in establishments with 500 or more employees; January 25, 1999, in establishments with 10 or more but fewer than 500 employees (unless the establishment has annual sales of less than \$2.5 million); and January 25, 2000, in establishments with fewer than 10 employees or annual sales of less than \$2.5 million.

Given the explicit requirements to list critical control points, critical limits, and monitoring and verification procedures and to develop and identify corrective actions, and the Agency's statement, in issuing part 417, that it was clarifying requirements for the identification of critical control points within a HACCP plan (61 FR 38825), FSIS is concerned that some industry members and consultants to industry think that they can comply with Sec. 417.2(c) by referring to good manufacturing practices, or establishment actions in accordance with good manufacturing practices. While FSIS has considered good manufacturing practices in developing some requirements that protect the public against livestock products and poultry products that are misbranded or economically adulterated (21 U.S.C. 453 and 601), the Agency has not adopted specific good manufacturing practices as part of its regulations.

The Agency is publishing this notice to ensure that the owners and operators of federally inspected establishments are aware that references to good manufacturing practices, or establishment actions in accordance with good manufacturing practices, rather than stating the critical control points, critical limits, monitoring and verification

procedures, and corrective actions themselves is insufficient to satisfy the requirements of Sec. 417.5(c). Part 417 requires that a HACCP plan be a self-contained document.

Moreover, the function of critical control points and critical limits is to prevent, eliminate, or reduce to an acceptable level one or more food safety hazards. By definition, critical limits are maximum and minimum values (Sec. 417.1), and by regulation, critical limits must be designed, at a minimum, to ensure that applicable targets or performance standards established by FSIS, and any other requirement in FSIS's regulations (9 CFR chapter III) pertaining to the specific process or product, are met (Sec. 417.2(c)(3)). To determine whether critical limits are met and, if not, prevent the distribution of adulterated food and future deviations, the regulations require plan-specific monitoring, verification, and corrective action procedures.

Done at Washington, D.C., on: January 26, 1998.

Thomas J. Billy,
Administrator.

[FR Doc. 98-2296 Filed 1-29-98; 8:45 am]
BILLING CODE 3410-DM-P

Establishment Review of Product Production Records

[Federal Register: March 6, 1998 (Volume 63, Number 44)]
[Rules and Regulations]
[Page 11104-11105]
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[DOCID:fr06mr98-3]

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 417

[Docket No. 98-003N]

Establishment Review of Product Production Records

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice on complying with the HACCP system regulations.

SUMMARY: The Food Safety and Inspection Service is publishing this document to provide information to owners and operators of federally inspected establishments about what actions they must take to comply with the requirement, in the hazard analysis and critical control point system regulations, to review the records associated with production of a product prior to its shipment for distribution. The regulations do not prescribe how establishments meet this requirement and, thus, are sufficiently flexible to accommodate various records' review schemes. However, establishments must determine that all critical limits were met and, when appropriate, that corrective actions were taken. Establishments must also ensure the completeness of their records before shipping the product for distribution.

FOR FURTHER INFORMATION CONTACT: Patricia F. Stolfa, Assistant Deputy Administrator, Regulations and

[[Page 11105]]

Inspection Methods, Food Safety and Inspection Service, Washington, DC 20250-3700; (202) 205-0699.

SUPPLEMENTARY INFORMATION: The Food Safety and Inspection Service (FSIS) administers a regulatory program under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.) to protect the health and welfare of consumers by preventing the distribution of livestock products and poultry products that are unwholesome, adulterated, or misbranded. To further the goal of reducing the risk of foodborne

illness from meat and poultry products to the maximum extent possible, FSIS issued part 417 of the regulations, Hazard Analysis and Critical Control Point (HACCP) Systems.*

* Part 417 requirements will apply as of January 26, 1998, in establishments with 500 or more employees; January 25, 1999, in establishments with 10 or more but fewer than 500 employees (unless the establishment has annual sales of less than \$2.5 million); and January 25, 2000, in establishments with fewer than 10 employees or annual sales of less than \$2.5 million.

Part 417 requires federally inspected establishments to determine the food safety hazards reasonably likely to occur in the production process and to develop and implement a HACCP plan, or plans, to control these hazards (Sec. 417.2(a), (b), and (c)). Under part 417, establishments control food safety hazards through monitoring procedures that apply critical limits at critical control points and, when deviations occur, by taking corrective actions that restore establishment control and keep adulterated food out of commerce, as documented in records that are subject to establishment verification (Secs. 417.2(c), 417.3, and 417.5).

To ensure that HACCP plans are implemented effectively and function as intended to control food safety hazards and prevent the distribution of adulterated livestock products and poultry products, part 417 also requires that establishments conduct validation and verification activities (Sec. 417.4(a)). Verification includes review of the records that the establishment must keep to document a HACCP plan in operation (Sec. 417.5(a)(3)). For a particular product, verification does not end until, in accordance with Sec. 417.5(c), the establishment has reviewed the records associated with its production.

Paragraph (c) of Sec. 417.5 provides that:

Prior to shipping product, the establishment shall review the records associated with the production of that product, documented in accordance with this section, to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of product. Where practicable, this review shall be conducted, dated, and signed by an individual who did not produce the record(s), preferably by someone trained in accordance with Sec. 417.7 of this part, or the responsible establishment official.

As federally inspected establishments prepare to implement HACCP plans under part 417, the Agency has received inquiries about what actions establishments must take to comply with this paragraph of the regulations. In particular, people have asked whether an establishment can satisfy the requirement for a final, records-based verification by using any procedure other than one in which a single reviewer looks at all the records for the product as it is assembled on the shipping dock and loaded for transportation from the establishment.

FSIS is publishing this notice to provide information to owners and operators of federally inspected establishments on the types of procedures that the Agency anticipates will satisfy this requirement. The essence of Sec. 417.5(c) is to require that establishments take responsibility not only for developing and implementing HACCP plans, but also for maintaining control of products until they ensure that

establishment personnel have applied those plans appropriately and effectively. FSIS has not prescribed how establishments comply, and it views the regulations as sufficiently flexible to accommodate records' review schemes in addition to the procedure described in the previous paragraph.

Establishment personnel can review production records at any point after processing and before shipment of the product, including, for example, at the end of the day of production before a product goes into on-site storage, while a product is in on-site storage, or during preparation of shipping documents before assembling product for transportation from the establishment. Consistent with the regulations, an establishment also can initiate checks for records' completeness earlier and accomplish the review in stages. For example, an establishment that slaughters and bones cattle carcasses one day and prepares ground beef the next could make one reviewer responsible for performing slaughter and boning records' review on the first day and carry the review forward to the second day, when another reviewer assumes responsibility for the remaining tasks necessary to ensure that there has been an establishment determination that all critical limits were met and, if appropriate, corrective actions were taken and that production records are otherwise complete and then signs and dates the review. In addition, establishments that maintain records on computers in accordance with Sec. 417.5(d) may be able to accomplish much of the record checking electronically.

The crucial concern is that there be verification that establishment controls have ensured proper product disposition, so that adulterated product is not distributed. FSIS has not, at this point, ruled out the possibility that a company might operate in compliance with this regulation despite the fact that the records-based verification is being conducted when the company transfers a product from the preparation establishment to another, storage location and holds the product there, maintaining control of the product, until the company completes the review and releases the product for shipment to retail outlets. Industry members interested in instituting a records' review scheme that includes this type of feature may wish to consult with the Agency about the types of safeguards needed to ensure that product is not shipped for distribution until the required verification is performed. (In Secs. 318.309(d)(1)(viii) and 381.309(d)(1)(viii), the canning and canned products' regulations address a similar situation as an exception, for which an establishment must obtain area supervisor approval, to the prohibition against shipping product from the establishments before the end of the required incubation period.) FSIS also notes that establishment compliance with part 417 requirements does not affect the applicability of section 10 of the FMIA or section 9(a) of the PPIA (21 U.S.C. 610 and 458(a)); in particular, transporting, or offering for transportation, adulterated livestock products or poultry products is prohibited.

Done at Washington, D.C., on: February 27, 1998.
Thomas J. Billy,
Administrator.
[FR Doc. 98-5770 Filed 3-5-98; 8:45 am]
BILLING CODE 3410-DM-P

HACCP Plan Requirements and Meat and Poultry Product Processing Categories; Policy Clarification

[Federal Register: April 1, 1998 (Volume 63, Number 62)]
[Rules and Regulations]
[Page 15739-15740]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr01ap98-1]

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Rules and Regulations

Federal Register

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The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

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[[Page 15739]]

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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 417

[Docket No. 98-006N]

HACCP Plan Requirements and Meat and Poultry Product Processing Categories; Policy Clarification

AGENCY: Food Safety and Inspection Service.

ACTION: Policy clarification.

SUMMARY: The Food Safety and Inspection Service (FSIS) is publishing this document to clarify its policy in regard to HACCP (Hazard Analysis and Critical Control Points) requirements for meat and poultry

establishments producing either multiple products that fall within a single processing category or single products that pass through multiple processing categories.

DATES: Comments must be received on or before June 1, 1998.

ADDRESSES: Submit one original and two copies of written comments to FSIS Docket Clerk, Docket #98-006N, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 102, Cotton Annex, 300 12 St., SW, Washington, DC 20250-3700. All comments submitted in response to this document will be available for public inspection in the Docket Clerk's Office between 8:30 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT:

Patricia F. Stolfa, Assistant Deputy Administrator, Regulations and Inspection Methods, Food Safety and Inspection Service, U.S. Department of Agriculture (202) 205-0699.

SUPPLEMENTARY INFORMATION:

Background

On July 25, 1996, FSIS published a final rule establishing new requirements intended to improve the safety of meat and poultry products and facilitate the modernization of USDA's meat and poultry inspection system ("Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems"; 61 FR 38806). The final rule requires all official meat and poultry establishments to implement HACCP, a science-based process control system. Under the new regulations, all official establishments are responsible for developing and implementing HACCP plans incorporating the controls necessary and appropriate to ensure that their meat or poultry products are safe.

HACCP is a flexible system that enables establishments to develop and implement control systems customized to the nature and volume of their production. Accordingly, FSIS has promulgated regulatory requirements meant to provide meat and poultry establishments with the maximum flexibility for developing and implementing HACCP plans. FSIS is publishing this notice to clarify the regulatory requirements for establishments that wish to develop and implement a single HACCP plan for multiple, similar products or for a single product that passes through multiple processing categories.

Under Sec. 417.2, paragraph (a) of the HACCP requirements, FSIS requires meat and poultry establishments to conduct a hazard analysis to determine what food safety hazards are reasonably likely to occur in the production process and identify the preventive measures it can apply to control those hazards. Whenever a hazard analysis reveals that one or more food safety hazards are reasonably likely to occur, FSIS requires that each establishment develop and implement a written HACCP plan covering each product produced by that establishment. Further, FSIS specifically requires that establishments develop HACCP plans for products that fall into the following processing categories:

- (i) Slaughter--all species.
- (ii) Raw product--ground.
- (iii) Raw product--not ground.
- (iv) Thermally processed--commercially sterile.
- (v) Not heat treated--shelf stable.

- (vi) Heat treated--shelf stable.
- (vii) Fully cooked--not shelf stable.
- (viii) Heat treated but not fully cooked--not shelf stable.
- (ix) Product with secondary inhibitors--not shelf stable.

Section 417.2(b)(2) states "A single HACCP plan may encompass multiple products within a single processing category identified in this paragraph, if the food safety hazards, critical control points (CCP's), critical limits, and procedures required to be identified and performed * * * are essentially the same, provided that any required features of the plan that are unique to a specific product are clearly delineated in the plan and are observed in practice." Many meat and poultry establishments, especially processing establishments, manufacture numerous products that have most of their processing steps in common. Allowing a single HACCP plan for such products was intended to simplify and improve both compliance and inspection.

For example, an establishment producing both ready-to-eat corned beef and ready-to-eat roast beef could develop and implement a single HACCP plan for both products. The HACCP plan would identify the common CCP's and critical limits (cooking and cooling product in accordance with time/temperature combinations predetermined by the establishment), as well as any processing differences (the corned beef would undergo a curing step). In this example, compliance with HACCP requirements is simplified, and it is probably more efficient and cost-effective to develop and implement a single HACCP plan for the two products than to produce two separate plans. Inspection is also improved and simplified because FSIS inspection personnel can more efficiently and effectively review a single, unified HACCP plan.

In this document, FSIS also is clarifying that meat and poultry establishments may develop a single HACCP plan for a single product that passes through multiple processing categories. It is likely that such HACCP plans would be developed and implemented, for the most part, by establishments that both slaughter (category (i)) and process (categories (ii) through (ix)) meat or poultry. For example, there are numerous establishments that slaughter, grind, and package meat for retail sale. There also are numerous establishments that slaughter, cut up, and package poultry for retail sale. Many of these and similar establishments probably will choose to develop and implement a single HACCP

[[Page 15740]]

plan covering both slaughter and processing. Developing and implementing a single HACCP plan for a single product often would be more efficient and cost effective than producing two plans (one for slaughter and one for processing). In many cases, FSIS inspection personnel will be able to more efficiently and effectively review a single HACCP plan that covers all of the processing (including slaughter) within a meat or poultry establishment.

Done in Washington, DC: March 18, 1998.
Thomas J. Billy,
Administrator, Food Safety Inspection Service.
[FR Doc. 98-8432 Filed 3-31-98; 8:45 am]
BILLING CODE 3410-DM-P

Listeria Monocytogenes Contamination of Ready-to-Eat Products

[Federal Register: May 26, 1999 (Volume 64, Number 101)]

[Rules and Regulations]

[Page 28351-28353]

From the Federal Register Online via GPO Access [wais.access.gpo.gov]

[DOCID:fr26my99-2]

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 416 and 417

[Docket No. 99-025N]

Listeria Monocytogenes Contamination of Ready-to-Eat Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Compliance with the HACCP system regulations and request for comment.

SUMMARY: The Food Safety and Inspection Service (FSIS) is publishing this document to inform manufacturers of ready-to-eat livestock and poultry products of the Agency's views about the application of the hazard analysis and critical control point (HACCP) system regulations to contamination with *Listeria monocytogenes*.

FSIS believes that the findings from testing a range of ready-to-eat products and information from investigations of outbreaks of listeriosis constitute changes that could affect an establishment's hazard analysis or alter the HACCP plan for affected products. Therefore, establishments must reassess their HACCP plans for ready-to-eat livestock and poultry products. If reassessment results in a determination that *Listeria monocytogenes* contamination is a food safety hazard reasonably likely to occur in the establishment's production process, then it is a type of microbiological contamination that must be addressed in a HACCP plan.

In this document, FSIS is setting out several factors that it believes an establishment should consider when performing its reassessment. Also, FSIS is making guidance material available that establishments may find helpful. (See ADDRESSES). FSIS invites comments on the factors addressed in this document and on its guidance material.

DATES: Comments may be submitted by July 26, 1999.

ADDRESSES: Submit one original and two copies of written comments to FSIS Docket Clerk, Docket No. 99-025N, U.S. Department of Agriculture,

Food Safety and Inspection Service, Room 102, Cotton Annex, 300 12th Street, SW, Washington, DC 20250-3700. All comments submitted in response to this document will be available for public inspection in the Docket Clerk's office between 8:30 a.m. and 4:30 p.m., Monday through Friday.

Guidance material is available from the Inspection Systems Development Division, FSIS, USDA, Room 202, Cotton Annex Building, 300 12th Street SW, Washington, DC 20250-3700, phone (202) 720-3219, Fax (202) 690-0824. The material is also available on the FSIS Homepage: <http://www.fsis.usda.gov/index.htm>

FOR FURTHER INFORMATION CONTACT: Daniel L. Engeljohn, Ph.D., Director, Regulations Development and Analysis Division, Food Safety and Inspection Service, Washington, DC 20250-3700; (202) 720-5627.

SUPPLEMENTARY INFORMATION:

Regulatory Context

The Food Safety and Inspection Service (FSIS) administers the regulatory program under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.) to protect the health and welfare of consumers by preventing the distribution of livestock and poultry products that are unwholesome, adulterated, or misbranded. To further the goal of reducing the risk of foodborne illness from livestock and poultry products to the maximum extent possible, FSIS issued the Pathogen Reduction-Hazard Analysis and Critical Control Point (HACCP) Systems final rule on July 25, 1996 (61 FR 38806). These regulations require federally inspected establishments to take preventive and corrective measures at each stage of the food production process where food safety hazards occur.

Part 416, the regulations on Sanitation Standard Operating Procedures (SOP's), requires establishments to develop, implement, and maintain written SOP's for sanitation that describe daily procedures that are sufficient to prevent direct contamination or adulteration of products (Sec. 416.11 and 416.12(a)). Part 417, the regulations on HACCP systems, requires a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures an establishment can apply to control those hazards in the production of particular products (Sec. 417.2(a)). Whenever a hazard analysis reveals one or more such hazards, the regulations require the establishment to develop and implement a written HACCP plan, for each product, that includes specified controls for each hazard so identified (Sec. 417.2(b)(1) and (c)).

When FSIS issued the Pathogen Reduction-HACCP Systems final rule, it responded to questions about the link between Sanitation SOP's and HACCP plans by noting the importance of Sanitation SOP's as tools for meeting existing sanitation responsibilities and preventing direct product contamination and adulteration and their appropriateness as near-term procedures--that is, for implementation prior to HACCP implementation and, in a sense, as a prerequisite to HACCP. In response to concerns about redundancy, the Agency noted that a sanitation procedure incorporated into a validated HACCP plan need not be duplicated in the establishment's Sanitation SOP's. FSIS also anticipated that some Sanitation SOP procedures, such as those addressing pre-operational cleaning of facilities, equipment, and

utensils were likely to remain in an establishment's Sanitation SOP's. (61 FR 38834.)

The HACCP system regulations require an official establishment to develop and implement a written HACCP plan whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur in the production process ((Sec. 417.2(a), (b)(1), and (c))). Paragraph (a)(1) of Sec. 417.2 specifies the purpose of a hazard analysis: ``to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards.'' Ten potential hazard areas, including microbiological contamination, are listed to guide establishments in this analysis (Sec. 417.2(a)(3)).

Section 417.2(a)(1) also provides that a food safety hazard is reasonably likely to occur if a prudent establishment would establish controls because the hazard historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls.

The likelihood that a potential food safety hazard will occur in the production process for a particular

[[Page 28352]]

product at a given location, and the identification and adequacy of preventive measures to control a likely hazard, must be determined by each establishment. Obviously, conditions may well change over time. For this reason, the HACCP system regulations require every establishment to reassess HACCP plan adequacy at least annually and whenever any changes occur that could affect the underlying hazard analysis or alter the HACCP plan (Sec. 417.4(a)(3)). When reassessment reveals that a plan no longer meets the requirements for the contents of a HACCP plan, the establishment must modify the plan immediately (Sec. 417.4(a)(3)).

Listeria Monocytogenes

Listeria monocytogenes is a type of pathogenic bacteria often found in the intestines of healthy animals (including humans) and in the environments in which food producing animals are raised and processed (e.g., in soil, water, and vegetation and on the surfaces of equipment, floors, and walls). Therefore, food may be contaminated with this microorganism and, after cooking or other treatment to destroy the pathogen, may be recontaminated.

Listeria monocytogenes can cause listeriosis, a serious and sometimes fatal illness, for which pregnant women, newborns, the elderly, and people with weakened immune systems are at risk. The most common manifestation of listeriosis is meningitis. It also can cause miscarriages and stillbirths. Advances in molecular subtyping methods have improved scientists' ability to associate Listeria monocytogenes with particular products and to detect outbreaks of listeriosis.

Since the late 1980's, FSIS and the Food and Drug Administration (FDA) have worked with food manufacturers to improve procedures for ensuring that ready-to-eat foods (i.e., products that may be consumed without any further cooking or other preparation) are free of Listeria monocytogenes. In addition, for the past decade, FSIS has conducted a microbiological testing program in which the Agency samples ready-to-eat livestock and poultry products, including cooked and fermented sausages, cooked corned beef, sliced ham and luncheon meats, beef

jerky, cooked uncured poultry, and salads and spreads, in federally inspected establishments. (For the Agency's current testing program instructions, see FSIS Directive 10,240.2, Microbial Sampling of Ready-to-Eat Products Produced by Establishments Operating Under a HACCP System.) FSIS treats ready-to-eat products in which *Listeria monocytogenes* is found as adulterated under the FMIA or the PPIA (21 U.S.C. 453(g) or 601(m)).

Between 1989 and 1993, the rate of illness from *Listeria monocytogenes* declined. Over the next several years, there did not appear to be any further decline, however, and since last fall, there has been an increase in the number of cases caused by a specific subtype--a previously rare ``E'' pattern--of *Listeria monocytogenes*. The Centers for Disease Control, U.S. Public Health Service, Department of Health and Human Services (DHHS), have reported 101 illnesses, 15 adult deaths and 6 stillbirths or miscarriages associated with this ``E'' pattern. Using methodological advances that provide more specific information about pathogens isolated from foods and humans, public health agencies have obtained information associating the ``E'' pattern subtype of *Listeria monocytogenes* with livestock and poultry products.

FSIS currently is evaluating a range of measures, both short- and long-term, to improve public health protection against this pathogen. In aid of this evaluation, FSIS held a public meeting on February 10, 1999, at which research, regulation, and education activities along with industry and government procedures, were discussed.

Controlling *Listeria Monocytogenes* Contamination

FSIS is publishing this document to advise federally inspected establishments of the Agency's current position on one aspect of the public health strategy to deal with *Listeria monocytogenes* contamination and to provide an opportunity to comment on that position as FSIS continues to develop a comprehensive strategy. FSIS is concerned because some establishments have not reassessed their HACCP plans after recent outbreaks of listeriosis caused by contaminated ready-to-eat livestock and poultry products, and after some establishments have produced ready-to-eat products adulterated with *Listeria monocytogenes*. If *Listeria monocytogenes* contamination is a food safety hazard reasonably likely to occur in an establishment's production process, then it must be addressed in a HACCP plan. It would not be sufficient to claim that the hazard is adequately dealt with in the establishment's Sanitation SOP. HACCP plan reassessment is necessary to determine whether the plan appropriately addresses this hazard.

FSIS views investigations of recent outbreaks of listeriosis and findings of *Listeria monocytogenes* contamination, along with other information now available on the prevalence and persistence of this foodborne pathogen, as sufficient evidence that some establishments' present approach to the food safety hazard presented by ready-to-eat livestock food and poultry products adulterated with *Listeria monocytogenes* does not comply with part 417 requirements. Therefore, FSIS believes that Sec. 417.4(a)(3) requires that establishments reassess the HACCP plans that cover ready-to-eat livestock and poultry products.

Put another way, the Agency does not see how--given the current record of contamination incidents and information now available on the prevalence and persistence of the microorganism, its ability to survive under adverse conditions, and the apparent susceptibility of some

products to contamination--an establishment that produces a ready-to-eat product (other than one that is thermally processed-commercially sterile, in accordance with part 318, subpart G, or part 381, subpart X, of the regulations) could have confidence that, in operation, the HACCP plan for the product meets part 417 requirements.

FSIS' conclusion addresses only the need for HACCP plan reassessment. FSIS cannot predict the likelihood that an establishment producing ready-to-eat products would be required under the regulations to incorporate, or alter, controls to prevent *Listeria monocytogenes* contamination in one or more HACCP plans as a result of plan reassessment. FSIS does believe, however, that given current knowledge, *Listeria monocytogenes* contamination should be considered to be reasonably likely to occur in the production of ready-to-eat livestock and poultry products, especially if an establishment has produced products adulterated with *Listeria monocytogenes*, or if the establishment is producing one or more ready-to-eat products that are susceptible to *Listeria monocytogenes* contamination in an environment that is not known to be free of this pathogen.

FSIS urges establishments that produce ready-to-eat livestock and poultry products to perform the reassessment of their HACCP plans within 30 days of the publication of this document. FSIS will instruct its inspection personnel to verify that reassessments were conducted. If an establishment does not reassess its HACCP plan in accord with this document, FSIS will evaluate the establishment's compliance with Part 417.

[[Page 28353]]

Set out below are factors that FSIS believes are relevant in determining whether *Listeria monocytogenes* contamination is a food safety hazard reasonably likely to occur in the production process and in identifying preventive measures that establishments can apply to control the hazard. Reassessments of HACCP plans should take these factors into account. FSIS is providing technical information and other Agency guidance material. (See ADDRESSES to obtain copies.) The Agency invites comments on this guidance material and the factors set out below.

(1) Pathogen Levels in Starting Materials FSIS believes that it is crucial that each establishment know the characteristics of its starting materials and, in particular, keep itself informed about evidence of *Listeria monocytogenes* contamination of the raw materials or source of raw materials that the establishments use.

(2) Validation of Lethality Treatment FSIS believes industry members must comply rigorously with the HACCP plan validation requirements of Sec. 417.4(a)(1), especially in ensuring that the establishment can successfully apply a scientifically appropriate lethality treatment under its commercial operating conditions (see 61 FR 38826-38827). Until the establishment demonstrates that it achieves the anticipated lethality effect under actual in-plant conditions, effectiveness is theoretical, and the plan is not validated.

(3) Exposure to Contamination After Lethality Treatment The available evidence on the presence of *Listeria monocytogenes* in food processing environments appears to indicate an increased potential for the contamination of product after a food is processed to destroy pathogenic microorganisms. Therefore, an establishment's reassessment of its HACCP plans needs to address such potential contamination. Establishments should account for finished product characteristics such

as water activity, pH, and the presence or absence of one or more barriers that inhibit pathogen growth. The HACCP plan must incorporate any hazards identified by the reassessment.

(4) Evidence of Product Contamination FSIS believes that any finding of *Listeria monocytogenes* in an establishment's ready-to-eat product, whether in government or industry test results, is substantial, and perhaps conclusive, evidence that *Listeria monocytogenes* contamination is a food safety hazard that is reasonably likely to occur in its production process for that product. Therefore, in the event of such a finding, FSIS' position is as follows. If the establishment's HACCP plan does not already provide for the control of *Listeria monocytogenes*, and absent substantial, scientifically supportable reasons, that HACCP plan must be modified to address the *Listeria monocytogenes* hazard and incorporate appropriate controls. If the establishment's HACCP plan does address and control for *Listeria monocytogenes*, the establishment must take the appropriate corrective actions in accord with the requirements of 9 CFR 417.3. FSIS inspection personnel will verify that the establishment has taken the necessary corrective actions.

Done at Washington, D.C., on May 19, 1999.

Thomas J. Billy,
Administrator.

[FR Doc. 99-13223 Filed 5-25-99; 8:45 am]

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